IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

MARTHA CARLSON,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-05475

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

Pending before the court are the following motions brought by the defendant: (1) Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 34]; (2) Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [Docket 38]; (3) Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 39]; (4) Motion to Exclude the Opinions and Testimony of Ron Luke, JD, Ph.D. [Docket 40]; (5) Motion to Exclude the Opinions and Testimony of Bobby L. Shull, M.D. [Docket 42]; (6) Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 43]; (7) Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 46]; (8) Motion to Exclude the Opinions and Testimony of Bruce Rosenzweig, M.D. [Docket 49]; (9) Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [Docket 50]; (10) Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 51]; (11) Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 52]; and (12) Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 56].

Also pending before the court are the following motions brought by the plaintiff: (1) Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 44]; (2) Motion to Exclude the Opinions and Testimony of Patrick Culligan, M.D. [Docket 45]; (3) Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [Docket 47]; (4) Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [Docket 48]; (5) Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. [Docket 55]; and (6) Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 57].

My rulings are set forth below.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 72,000 cases currently pending, approximately 16,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Martha Carlson, was surgically implanted with the Uphold Vaginal Support System ("Uphold"), a mesh product manufactured by BSC to treat POP. Ms. Carlson received her surgery at Carolinas Medical Center in Charlotte, North Carolina, on July 16, 2010. (Short Form Compl. [Docket 1], at 4). She now claims that as a result of the implantation of the Uphold, she has experienced various complications and injuries. The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; discovery rule, tolling, and fraudulent concealment; and punitive damages. (*Id.* at 4-5). The parties have retained experts to render

opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States*

v. Moreland, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94). Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, the second part of the analysis, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

III. Preliminary Matters

Before I review these motions, I begin by addressing a few preliminary matters that affect many of the *Daubert* motions. First, both parties consistently challenge experts' opinions as improper state-of-mind or legal-conclusion testimony. As I have maintained throughout these MDLs, I will not permit the use of experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013) (excluding expert opinions on the defendant's knowledge, state of mind, alleged bad acts, failures to act, and corporate conduct and ethics). The reasonableness of conduct and a party's then-existing state of mind "are the sort of questions that lay jurors have been answering without expert assistance from time immemorial," and therefore, these matters are not appropriate for expert testimony. *Kidder v. Peabody & Co. v. IAG Int'l Acceptance Grp., N.V.*, 14 F. Supp. 2d 391, 404 (S.D.N.Y. 1998), *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony.").[1] Likewise, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). An expert may not state his opinion using "legal terms of art," such as "defective,"

[1] On a related note, I caution the parties against introducing corporate evidence through expert witnesses. Although an expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—he may not be offered solely as a conduit for corporate information. There is no reason why the plaintiff requires an expert to opine on such facts.

"unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

I have diligently applied these rules to previous expert testimony, and I continue to adhere to them in this case. This does not mean, however, that each objection to state-of-mind or legal-conclusion testimony raised in these motions is valid. But I will not parse the numerous reports and thousand-page depositions for each expert to determine the validity of these same objections. Instead, the onus is on counsel to tailor expert testimony at trial in accordance with the above directive. Therefore, unless otherwise necessary, the remainder of this opinion does not address objections brought against an expert based on improper state-of-mind or legal-conclusion testimony.

I also note that several of the *Daubert* motions concern expert opinions entirely unrelated to the individual plaintiff at bar. For example, some experts have opined on general and specific causation with the specific causation portion of the opinion pertaining to wave plaintiffs other than Ms. Carlson. In addition, the parties filed a total of *eighteen Daubert* motions involving, in many instances, duplicative experts. In an effort to remedy this problem of blanketed, duplicative *Daubert* motions, I directed the parties to file disclosures, indicating who, out of the eighteen challenged experts, they plan to call at trial for each case. (*See* Pretrial Order # 121 [Docket 58], at 5–6). Through these disclosures, I hoped to gain a better understanding of the particular arguments at issue, thereby refining my *Daubert* rulings for the benefit of the transferor judge. Rather than aiding the court in this endeavor, however, the parties have effectively ignored my pretrial order, identifying seventeen of the eighteen challenged experts as probable expert witnesses. (*See* BSC's Disclosure Required by Pretrial Order # 121 [Docket 60]; Pl.'s Disclosure Required by Pretrial Order # 121 [Docket 61]). Without guidance from the parties to the

contrary, I have thus limited my review of the *Daubert* motions to only those arguments and opinions related to the instant plaintiff. In other words, I disregard arguments included in the briefing directed exclusively at other wave plaintiffs and, consequently, irrelevant to Ms. Carlson's case.

Finally, I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __ (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __ (S.D. W. Va. 2014), *available at* 2014 WL 5461991. The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of an expert's opinion based on its reliability and relevance. In other words, the parties have comparatively examined each expert's opinions and have largely overlooked *Daubert*'s core considerations for assessing expert testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsel's expectations that I align with these previous rulings when faced with a different record are remiss, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper of expert testimony, as well as my duty to "respect[] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to entertain *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert opinions and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light

of the particular opinions and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the opinions contained therein.

Having addressed these preliminary matters, I now turn to BSC's *Daubert* motions.

IV. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude the expert opinions of Drs. Michael Thomas Margolis, Niall Galloway, Thomas H. Barker, Ron Luke, Bobby L. Shull, Jimmy W. Mays, Russell Dunn, Bruce Rosenzweig, Peggy Pence, Richard Trepeta, Scott Guelcher, and Vladimir Iakovlev.

A. Michael Thomas Margolis, M.D.

BSC seeks to exclude the testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist who offers general causation opinions in this case. (*See* Ex. A, Margolis Report [Docket 34-1], at 1–26). BSC argues that his opinions are unreliable because he failed to consider contrary scientific literature and failed to provide any scientific basis for his other opinions. Also, BSC argues that Dr. Margolis seeks to offer opinions beyond his expertise.

1. BSC Argues that Dr. Margolis Failed to Consider Contrary Scientific Studies in Forming His Opinions

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f

the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; *see also Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co.*, CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

a. Opinion that Polypropylene Mid-Urethral Slings Are Not Safe and Effective for SUI

BSC argues that Dr. Margolis's opinion that polypropylene mid-urethral slings are not safe and effective for the treatment of SUI is unreliable because he ignored peer-reviewed literature indicating otherwise. Nevertheless, at issue in this case is a POP product. Dr. Margolis's opinion is about the treatment of SUI, and, therefore, his opinion is irrelevant to the plaintiff's claims. As a result, Dr. Margolis's opinion as to this matter is **EXCLUDED**. This aspect of BSC's motion is **GRANTED**.

b. Opinion Regarding the Complication Rates of Pain in Women with Polypropylene Mesh and Slings

BSC next challenges Dr. Margolis's opinion that there is a greater than 50% complication rate of pain in women with polypropylene mesh and slings. BSC contends that he fails to provide a scientific basis for disagreeing with studies that find lower pain rates. Dr. Margolis merely

discounts those studies "[b]ecause that's not what [he] ha[s] seen, read, studied, observed, and that's not biologically plausible." (*See* Ex. E, Margolis Dep. (Jan. 6, 2014) [Docket 34-2], at 239:11–13).

In his deposition, Dr. Margolis acknowledges that contrary studies exist, (*see id.* at 239:2–6), and I do not doubt that Dr. Margolis reviewed contrary studies. However, his methodology may be flawed if he does not provide an adequate explanation for why he disagrees with those studies. The plaintiff has failed to identify such an explanation in this case. Therefore, Dr. Margolis's opinion that more than 50% of women implanted with mesh experience pain is **EXCLUDED** as unreliable. This aspect of BSC's motion is **GRANTED**.

c. Opinions Regarding General Complication Rates in Women with Polypropylene Mesh

BSC also challenges Dr. Margolis's general opinions that complications in women with polypropylene mesh products are high. BSC contends that Dr. Margolis disregards literature revealing single digit dyspareunia complication rates without sufficient explanation. In his deposition, Dr. Margolis discounts these studies by alleging that the complications are underreported, that the studies are inaccurate, and that the data is possibly fabricated. (*Id.* at 241:12–20). Moreover, Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." (*Id.* at 259:8–9). In other words, he "assume[s] the worse-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. (*Id.* at 259:11–19). "[G]iv[ing] the benefit of the doubt to the patient" is not a reliable, scientific basis for determining the complication rates associated with a mesh device. (*Id.* at 259:8–9). The plaintiff has failed to demonstrate that Dr. Margolis has sufficient scientific support to opine as to these generalized

statements. Therefore, this testimony is **EXCLUDED**, and this part of BSC's motion is **GRANTED**.

2. BSC Argues That Dr. Margolis Failed to Provide Any Scientific Basis For His Other Opinions

BSC also argues that Dr. Margolis failed to provide any scientific basis for his other opinions and that he based these opinions on his personal experience alone. The plaintiff does not address the majority of BSC's arguments here. Instead, in a generalized fashion, she states in a paragraph that Dr. Margolis should be allowed to testify about his personal experience. (Pl.'s Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. ("Pl.'s Resp. re: Margolis") [Docket 78], at 13–14). BSC interprets such a response as the plaintiff's concession.

I decline to raise counterarguments for the plaintiff when she has failed to address BSC's arguments in her briefing. Dr. Margolis may not solely rely on his personal observations, especially when he seeks to provide broad opinions, such as the infection rate in women with mesh. *See Daubert*, 509 U.S. at 592 (stating that Rule 702 permits "an expert [to offer] wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation" due to the "assumption that the expert's opinion will have a reliable basis in the knowledge and experience of his discipline"). "Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Id.* at 590. The plaintiff has not "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Therefore, the following opinions from Dr. Margolis are **EXCLUDED**: (1) that the Burch procedure is more effective than polypropylene mesh slings; (2) that Xenform slings are more effective than polypropylene slings; (3) that the infection rate of polypropylene mesh is up

to 100%; (4) that the complication rate of urethral obstruction is greater than 10% with polypropylene mid-urethral slings; and (5) that he has removed 10 to 15% of BSC products. These portions of BSC's motion are **GRANTED**.[2]

Unlike the above opinions, the plaintiff appears to respond to BSC's argument concerning Dr. Margolis's opinion about a lack of scientific support for the use of mesh. In his report, Dr. Margolis opines that there is a lack of sound scientific data supporting the use of mesh in the treatment of both SUI and POP. (Ex. A, Margolis Report [Docket 34-1], at 21). First, I **EXCLUDE** this opinion with respect to SUI because it is irrelevant to this POP case.[3]

As for the reliability of this opinion with respect to POP, BSC contends that Dr. Margolis's opinion should be excluded because Dr. Margolis contradicted himself during his deposition. In response, the plaintiff argues that BSC misinterprets Dr. Margolis. The plaintiff contends that Dr. Margolis merely opines that there is a lack of *long-term* data. Contradictions in testimony should be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir. 1994) ("[E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses . . . ."). Therefore, I do not exclude Dr. Margolis's opinion on a lack of *long-*

[2] I have previously excluded opinions (2) through (5) on reliability grounds. *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *16-18 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *10-12 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *see Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *12-13 (S.D. W. Va. 2014), *available at* 2014 WL 5461991 (addressing only opinions (3) and (5)). I have previously excluded opinion (1) on relevancy grounds in *Sanchez*, a POP case. *See Sanchez*, 2014 WL 4851989, at *15.

[3] I note that BSC's motion only challenges this opinion with respect to SUI, even though this case involves BSC's POP product. (BSC's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. ("BSC's Mem. re: Margolis") [Docket 35], at 6). It is careless on the part of BSC to challenge this opinion with respect to SUI only. However, the plaintiff in her response and BSC in its reply argue as if BSC had challenged this opinion with respect to POP as well. The court will accept the parties' interpretation and analyze this opinion as it relates to POP.

term data on reliability grounds.[4] Therefore, BSC's motion regarding this opinion is **GRANTED in part**, with respect to Dr. Margolis's opinion on this matter concerning SUI, and **DENIED in part**, with respect to Dr. Margolis's opinion on this matter concerning POP.

3. BSC Argues that Dr. Margolis's Opinions are Outside His Area of Expertise

BSC argues that Dr. Margolis offers opinions outside the scope of his qualifications on "(1) biomaterials; (2) polypropylene degradation; (3) chronic foreign body reaction; (4) adequate pore size; (5) adequate weight of polypropylene; (6) biocompatibility of polypropylene; (7) medical device design and development; and/or (8) marketing." (BSC's Mem. re: Margolis [Docket 35], at 15). In her response, the plaintiff states that "[t]o the extent that Dr. Margolis' opinions regarding biomaterials, medical device design, development, and marketing are outside of his expertise and experience, Dr. Margolis will be instructed to limit his opinion and avoid these areas. However, Plaintiffs' [sic] stipulation is only as to these limited areas outside of his expertise." (Pl.'s Resp. re: Margolis [Docket 78], at 14).

In its reply, BSC states that this concession is "unclear[.]" (BSC's Mem. of Law in Reply to Pl.'s Opp'n to Def.'s Mot. to Exclude the Ops. & Test. of Michael Thomas Margolis, M.D. [Docket 87], at 5). I find that the plaintiff's response explicitly concedes that Dr. Margolis will not offer opinions on topics 1, 7, and 8 listed by BSC. Further, the remaining topics 2 through 6 fit within at least one of the categories listed by the plaintiff. (Pl.'s Resp. re: Margolis [Docket 78], at 14). In terms of the concession's qualifying language—*i.e.*, to the extent these subjects are outside of Dr. Margolis's expertise, "Dr. Margolis will be instructed to limit his opinion and

[4] The plaintiffs in prior cases have responded to this same challenge in a different way. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *14 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *9 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *11 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. Instead of focusing on long-term data, those plaintiffs informed the court that Dr. Margolis never opined that there was *no* data supporting the benefits of polypropylene mesh, but just that there was no *credible* data on this subject. In those cases, I excluded Dr. Margolis's opinion because "it [was] still unclear why Dr. Margolis believe[d] th[o]se studies lack[ed] credibility." *Sanchez*, 2014 WL 4851989, at *14.

avoid these areas," (*id.*)—the court declines to engage in analyzing the plaintiff's intentional ambiguity. The plaintiff fails to provide any argument addressing how Dr. Margolis is an expert on any of the above subject matters, beyond the basic assertion that "Dr. Margolis is an established urogynecologist with years of experience with pelvic mesh products." (*Id.*). I need not make such arguments for them. Therefore, this aspect of BSC's motion is **GRANTED**.

4. Opinions Offered by Dr. Margolis That Were Not Disclosed in His Expert Report

Finally, BSC argues that Dr. Margolis seeks to offer opinions that were not disclosed in his expert report and that Dr. Margolis seeks to discuss materials that were not cited to in his expert report. Rule 26 requires an expert report to contain "a complete statement of all opinions the witness will express and the basis and reasons for them[.]" Fed. R. Civ. P. 26(a)(2)(B)(i). The plaintiff does not provide a response to this argument.

First, BSC notes that Dr. Margolis's expert report does not include his opinions "on the preferred weight of mesh and immune system response[.]" (BSC's Mem. re: Margolis [Docket 35], at 17). I disagree. In his report, Dr. Margolis notes several BSC documents discussing the weight of mesh and other mesh design features. (*See* Ex. A, Margolis Report [Docket 34-1], at 11-13). Then, Dr. Margolis states:

> I agree with the statements made from Boston Scientific in its 2012 National Sales Meeting memo in that polypropylene mesh is not inert within the body, mesh shrinkage of up to 20-50% occurs, surface area is directly related to subsequent infection and complications, *a reduction in materials that come in contact with the body reduces foreign body reactions and complications,* nerve destruction by mesh leads to chronic pain, and that shrinkage of connective tissue formation (scarring and bridging) leads to complications including pain.

(*Id.* at 13 (emphasis added)). Thus, I find that Dr. Margolis's opinions on the weight of mesh and the associated complications are sufficiently disclosed. I decline to exclude his opinions on this matter on Rule 26 grounds.

BSC also argues that Dr. Margolis cited at his deposition "to a power point presentation and over 16 new articles that were not included in his report or the attachments thereto." (BSC's Mem. re: Margolis [Docket 35], at 17). BSC attaches to its motion a list of 5 deposition transcripts, 1 U.S. Patent Publication, 36 BSC documents, and 42 scientific articles that were not included in Dr. Margolis's expert report or relied-upon list. (Ex. G, Margolis Nondisclosure List [Docket 34-2], at 1-6). Testimony on direct examination using such undisclosed sources as support for his opinions is **EXCLUDED** on Rule 26 grounds. However, the court notes that the following articles that BSC alleges were not disclosed are, in fact, included in Dr. Margolis's relied-upon list: (1) Feiner, B., et al., *Vaginal Mesh Contraction: Definition, Clinical Presentation and Management*; (2) Maher, C., et al., *Surgical management of pelvic organ prolapse in women*. (*See* Ex. A, Margolis Report, [Docket 34-1], at Appendix C). Dr. Margolis's testimony on these two articles is not excluded under *Daubert*.[5]

Therefore, I find that such aspect of BSC's motion is **GRANTED IN PART** and **DENIED IN PART**.

Therefore, for the reasons stated above, I **GRANT in part** and **DENY in part** BSC's Motion to Exclude the Testimony of Michael Thomas Margolis, M.D. [Docket 34].

B. Niall Galloway, M.D.

Dr. Niall Galloway is an Associate Professor of Surgery (Urology) at the Emory University School of Medicine in Atlanta, Georgia, whose practice consists largely "of handling complications resulting from the placement of synthetic mesh in the vagina for POP and SUI."

[5] BSC also states that any opinions that Dr. Margolis based on Laura Angelini's deposition should be excluded because the transcript "was not produced and plaintiffs' [sic] counsel would not agree to produce it." (BSC's Mem. re: Margolis [Docket 35], at 18). I decline to exclude these opinions on Rule 26 grounds. Laura Angelini's deposition is listed in Dr. Margolis's relied-upon list attached to his Rule 26 expert report. (Ex. A, Margolis Report [Docket 34-1], at Appendix C). Whether or not the plaintiff's counsel will provide BSC with this transcript is a discovery matter.

(Ex. 1, Galloway Report [Docket 38-1], at 2). On behalf of Ms. Carlson, Dr. Galloway offers a general causation opinion, which BSC now seeks to exclude.

1. Biomaterials

First, BSC argues that Dr. Galloway is not qualified to opine on biomaterials and that his opinions are unreliable. With regard to his qualifications, BSC points to Dr. Galloway's deposition testimony where he states that he is not an expert in biomaterials. (BSC's Mot. to Exclude the Ops. & Test. of Niall Galloway, M.D. & Its Mem. in Supp. ("BSC's Mot. re: Galloway") [Docket 38], at 5). However, this testimony is not dispositive. *See Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *36 (S.D. W. Va. July 8, 2014) (finding Dr. Johnson qualified to opine about polypropylene notwithstanding his deposition testimony "Q: Okay. You're not a biomaterials expert, are you? A: Um, I'm a clinical medical expert."). I have previously found certain medical doctors qualified to opine as to polypropylene. *See Jones v. Bard, Inc.*, No. 2:11-cv-00114, [Docket 391], at 6–9 (finding Dr. Ostergard qualified to opine as to polypropylene and product design)); *see also Huskey*, 2014 WL 3362264, at *35–37 (finding Dr. Johnson qualified to opine as to mesh degradation).

Like the physicians in these prior cases, Dr. Galloway is an accomplished urologist with years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. (*See* Pl.'s Opp'n to BSC's Mot. & Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Dr. Niall Galloway, M.D. [Docket 76], at 6 ("His opinions are founded on a deep understanding of anatomical processes as they related to permanent surgical implants, along with his clinical observations from performing hundreds of revision and removal procedures involving mesh.")). Dr. Galloway's clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its

degradation, leaching, shrinkage, and contraction. Accordingly, BSC's motion with regard to Dr. Galloway's qualifications is **DENIED**.

BSC also contends that Dr. Galloway's opinions are unreliable. However, the only support BSC offers for this contention is a portion of Dr. Galloway's deposition where he states that he cannot recall whether he reviewed BSC's biocompatibility testing. (*See* BSC's Mot. re: Galloway [Docket 38], at 6–7). Dr. Galloway's failure to review BSC's biocompatibility testing does not sufficiently undermine the reliability of his opinions and is an issue better suited for cross-examination. Accordingly, BSC's motion with regard to the reliability of Dr. Galloway's biomaterials opinions is **DENIED**.

2. Material Safety Data Sheet ("MSDS")

Next, BSC argues that Dr. Galloway is not qualified to opine on the Medical Application Caution contained in the MSDS for the polypropylene resin used to manufacture the Uphold. Specifically, BSC seeks to exclude two of Dr. Galloway's opinions on this topic:

> (1) I have seen no evidence that Boston Scientific disclosed this information to doctors and patients, nor did Boston Scientific seek further information, or do appropriate testing to determine the validity of these warnings. This is information that doctors and patients are entitled to know and need to know in order to make informed decisions regarding treatment options. Without complete and accurate information, informed consent is not possible.
>
> (2) In my opinion, placing a material that degrades, releases potentially toxic chemicals, creates a chronic inflammatory response, and was advised against by the manufacturers of the raw component represents a serious flaw in the design of Boston Scientific's transvaginal mesh devices.

(Ex. 1, Galloway Report [Docket 38-1], at 9–10). With regard to Dr. Galloway's first opinion, his discussion of BSC's corporate conduct will not be helpful to the jury and is thus **EXCLUDED**. However, Dr. Galloway is qualified, as a physician, to opine that information regarding the Medical Application Caution is critical to the informed consent process. With

regard to the second opinion, Dr. Galloway is not using his "scientific, technical, or other specialized knowledge" to make the factual statement that the manufacturers of polypropylene advised against permanent use, as BSC purports. Fed. R. Evid. 702. Instead, Dr. Galloway is using the information provided in the Medical Application Caution to support his opinions on design defect, which, as discussed more fully *supra*, he is qualified to do. Accordingly, the remainder of BSC's motion with regard to the MSDS is **DENIED**.

3. Design & Adequacy of Warnings

Next, BSC contends that Dr. Galloway is not qualified to opine on the design or adequacy of warnings of polypropylene transvaginal mesh devices. With regard to design, BSC highlights the fact that Dr. Galloway does not have any experience implanting the Uphold or any other polypropylene transvaginal mesh device. However, I agree with the plaintiff that Dr. Galloway's experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him in this case. Furthermore, Federal Rule of Evidence 702 does not necessarily require specific clinical experience implanting the device at issue. *See Thomas J. Kline, Inc. v. Lorillard*, Inc., 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion."); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *4–5 (S.D. W. Va. July 8, 2014) (finding expert qualified to offer general causation opinions despite his lack of specific experience with the product at issue). Accordingly, BSC's motion with regard to Dr. Galloway's opinions on product design is **DENIED**.

With regard to warnings, BSC only points to one "inadmissible" opinion: "By alphabetizing [complications in the Uphold's Directions for Use ("DFU")], rather than listing in

order of importance (as is the convention), BSC further trivializes the importance of these adverse events." (Ex. 1, Galloway Report [Docket 38-1], at 28–29). In support of this argument, BSC highlights Dr. Galloway's lack of familiarity with FDA regulations and requirements for warnings. This argument is unpersuasive because Dr. Galloway does not appear to rely on the FDA in arriving at his opinion. Upon independent review, however, I nevertheless find that Dr. Galloway's opinion regarding alphabetization is nothing more than his personal belief. Although Dr. Galloway states that listing complications in order of importance is "convention," he fails to provide any scientific basis for this statement. Therefore, the court has no way of assessing its reliability. Accordingly, BSC's motion with regard to warnings is **GRANTED**, and this opinion is **EXCLUDED**.[6]

4. Risk/Benefit Analysis

Next, BSC contends that Dr. Galloway provides no factual basis for his opinion that the risks of polypropylene always outweigh the benefits. In support of its position, BSC cites a portion of Dr. Galloway's deposition testimony where he states "that there are situations, although rare, in which the benefits might outweigh the risks." (Ex. 9, Galloway Dep. [Docket 38-9], at 174:7–8). The opinion BSC seeks to exclude comes from the section of Dr. Galloway's report discussing his review of the literature on transvaginally placed surgical meshes. (*See* Ex. 1, Galloway Report [Docket 38-1], at 19–23). Drawing on his clinical experience and review of relevant literature is a sufficiently reliable method of forming the opinion that the risks of polypropylene outweigh the benefits. For purposes of *Daubert*, the fact that Dr. Galloway

[6] To the extent BSC seeks to exclude other warnings opinions, I find that as a urologist, Dr. Galloway is qualified to testify about the risks of implanting the Uphold and whether those risks were adequately expressed in the Uphold's DFU. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)).

acknowledges the mere possibility of a situation where a particular patient might benefit from transvaginal mesh surgery does not undermine his overall opinion, which he clarifies by stating "that for the great majority of patients, the long-term risks do outweigh the benefits." (Ex. 9, Galloway Dep. [Docket 38-9], at 174:11–13). Accordingly, BSC's motion with regard to Dr. Galloway's risk/benefit analysis is **DENIED**.

5. Polypropylene Degradation

Next, BSC argues that Dr. Galloway provides no basis for his opinion that polypropylene degrades. Specifically, BSC objects to the conclusions that Dr. Galloway makes based on the *Clave* study. However, the "analytical gap between the data and the opinion," if any, is not so great that the opinions must fail under *Daubert*. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). As the gatekeeper of expert testimony, I must not concern myself with the "correctness of the expert's conclusions" and should instead focus on the "soundness of his methodology." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("*Daubert II*"); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) ("The court need not determine that the proffered expert testimony is irrefutable or certainly correct."). Here, Dr. Galloway considered and analyzed multiple scientific articles—not just the *Clave* study—and drew on his clinical experience to reach his opinion that polypropylene degrades. This is a reliable, scientific methodology. *See Monsanto Co. v. David*, 516 F.3d 1009, 1015 (Fed. Cir. 2008) ("[N]umerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts."). Any inconsistencies or discrepancies in his testimony go to its weight, not its admissibility, and BSC is free to capitalize on these matters during cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the

burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Accordingly, BSC's motion with regard to polypropylene degradation is **DENIED**.

6. Trocars

Next, BSC contends that Dr. Galloway's opinions on trocars, the instrument used to implant certain transvaginal mesh devices, should be excluded because the implantation of the Uphold does not require the use of a trocar. In response, the plaintiff concedes that Dr. Galloway's opinions related to the use of trocars will only be offered if the case involves the use of a trocar. Accordingly, BSC's motion with regard to trocars is **GRANTED**.

7. Relevant Literature

Lastly, BSC argues that Dr. Galloway's opinions are not tied to the facts of this case because he only reviewed one scientific article that specifically references the Uphold. As discussed more fully *infra* related to Dr. Badylak, if there are certain device-specific publications that Dr. Galloway failed to review in preparing his expert report, BSC is free to inquire about those publications on cross-examination. Accordingly, BSC's motion with regard to literature is **DENIED**.

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Niall Galloway, M.D. [Docket 38] is **GRANTED in part** and **DENIED in part**.

C. Thomas H. Barker, Ph.D.

BSC seeks to exclude the testimony of Thomas H. Barker, Ph.D. The plaintiff offers Dr. Barker as a biomaterials expert. He seeks to testify as to general opinions, such as those related to the biocompatibility of polypropylene mesh, mesh degradation, scar formation, mesh design, and mesh testing. (*See* Ex. D, Barker Report [Docket 39-1], at 4–7). BSC argues that Dr. Barker's opinions are unreliable because he lacks sufficient scientific support and because his

opinions are litigation driven. BSC also contends that Dr. Barker is unqualified to opine on polypropylene generally and on design and testing. In forming his opinions, Dr. Barker relied upon the scientific literature, his experience, and corporate documents. (*See id.* at Ex. B (relied-upon list)).

1. Reliability

a. Opinion on a Mechanical Mismatch Between Mesh and the Human Body

Dr. Barker opines that there is a mechanical mismatch between vaginal tissue and BSC mesh. (*See, e.g.*, Ex. D, Barker Report [Docket 39-1], at 5). I find this opinion to be unreliable. In comparing the elastic moduli of vaginal tissue to that of mesh in order to support his opinion as to a mismatch, Dr. Barker relied on a study finding 6 to 7 kilopascals for vaginal tissue. (Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 39-1], at 84:13–16). However, he admits that he has no scientific basis for forming a kilopascal number for BSC mesh. (*Id.* at 105:3–14). Moreover, Dr. Barker admits that, although "[t]here's significant evidence in the medical literature that there are regimes that the mesh is not mechanically matched with vaginal tissue . . . the studies were never done, so we can't say for sure." (*Id.* at 108:10–22). He also testifies that "there's certainly data to suggest that the mesh gets significantly stiff under load" but then concedes that, "without proper testing, it's everyone's guess." (*Id.* at 111:13–14). Such an opinion rests on an unreliable basis. To the extent that Dr. Barker merely opines that vaginal tissue and polypropylene mesh are not composed of the same material, such an opinion is not helpful to a jury. Dr. Barker's opinion that a mechanical mismatch exists is **EXCLUDED**.

b. Opinions on the Clinical Significance of His Mechanical Performance Findings

Dr. Barker's opinions on the clinical consequences resulting from the alleged mechanical mismatch between the mesh and the human body are **EXCLUDED** as unreliable as well. (*See,*

e.g., Ex. D, Barker Report [Docket 39-1], at 6–7). His opinion on the mechanical mismatch generally is excluded, and, thus, any derivative opinions of such are also unreliable. Dr. Barker testified that testing would need to be done in order to determine the effect that an implant may have in vivo. (*See* Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 39-1], at 97:21–1). However, he also states that no one has performed this testing for transvaginal mesh. (*See id.* at 98:2–7). Concluding that mesh degrades, deforms, or causes scarring in the human body based on speculation that there is a mechanical mismatch between vaginal tissue and BSC mesh fails to survive *Daubert* scrutiny. Moreover, in forming these in vivo opinions, Dr. Barker relied on a mesh study performed ex vivo, where the authors explicitly state that their study does not conclusively reveal the mesh's behavior in the human body. (*See* Ex. F, Shepard, JP et al., *Uniaxial Biomechanical Properties of Seven Different Vaginally Implanted Meshes for Pelvic Organ Prolapse*, 23 Int'l Urogynecology J. 613, 619 (2012) [Docket 96-6] (stating that "the experimental setup allows us to draw only preliminary conclusions about the various meshes")). Such opinions are too speculative to be deemed reliable under *Daubert*.

Moreover, with respect to mesh deformation in particular, BSC challenges Dr. Barker's opinion that BSC testing revealed approximately 35% to 52% of deformation in its mesh samples. (Ex. E, Barker Dep. (Dec. 15, 2014) [Docket 39-1], at 135:14–136:3). Dr. Barker bases this opinion on a BSC email. However, when questioned about this topic, Dr. Barker admitted that he is unsure whether this testing was done exclusively on BSC products. (*See id.* at 137:15–138:2). This deposition testimony further reveals the unreliability of Dr. Barker's methodology. BSC's motion with respect to Dr. Barker's opinions on the clinical effects of a mechanical mismatch between BSC mesh and vaginal tissue is **GRANTED**.[7]

[7] In her response, the plaintiff contends that BSC does not challenge Dr. Barker's opinions "that the mesh used in the BSC products was not designed to maintain its properties when placed in the body" and that the

In conclusion, BSC's Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 39] is **GRANTED**.[8]

D. Ron Luke, JD, Ph.D.

The plaintiff has indicated that she does not intend to call Dr. Luke at trial. (Disclosure Required by PTO # 121 [Docket 61]). Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Ron Luke, JD, Ph.D. [Docket 40] is **DENIED as moot**.

E. Bobby L. Shull, M.D.

Dr. Bobby Shull is a urogynecologist offered by the plaintiff to provide expert opinion testimony on the design and labeling of the Uphold. BSC moves to exclude several of Dr. Shull's opinions on *Daubert* grounds, and I address BSC's arguments in turn.

1. Opinions on Product Design

First, BSC argues that Dr. Shull's opinions on the design of the Uphold should be

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"biocompatibility of a specific biomaterial is specific to a particular area of the body, which will respond in its own particular fashion." (Pl.'s Opp'n to Def. BSC's Mot. & Mem. of Law in Supp. to Exclude Ops. & Test. of Dr. Thomas Barker, Ph.D. [Docket 72], at 11). However, this statement is incorrect. BSC addresses these two opinions in its original motion, when challenging Dr. Barker's opinions on the clinical significance of a mechanical mismatch.

[8] As for qualifications, Dr. Barker holds a Ph.D. in biomedical engineering and is currently on the faculty of a joint department within the Georgia Institute of Technology and Emory University School of Medicine. He states in his expert report that his research focuses on

> the effects of mechanical forces and tissue/material mechanical properties (e.g. stiffness) on the host response. I am trained and have extensive expertise in the evaluation of biomaterial mechanical properties, biomaterial/implant design, the foreign body host response, and human tissues under repair and fibrosis, including analyses of cell/molecular biological outcomes.

(Ex. D, Barker Report [Docket 39-1], at 3). Dr. Barker conducted postdoctoral research focusing on "exploring the mechanisms of biomaterial associated fibrosis (e.g. the foreign body response)." (*Id.* at 2). Additionally, Dr. Barker has authored several book chapters and peer-reviewed articles. (*Id.* at 3).

I do not doubt Dr. Barker's qualifications in the field of biomedical engineering. However, I need not address them because I find Dr. Barker's opinions to be unreliable. Even if an expert is highly qualified, an analysis of the reliability of that expert's methodology is required. *See Daubert*, 509 U.S. at 597 (explaining that the Federal Rules of Evidence "do assign the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"). Qualifications alone do not guarantee reliability. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3–5 (S.D. W. Va. Oct. 11, 2007) (excluding opinions of a "very qualified" expert because the basis for the testimony was unreliable). "[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method." *Daubert*, 509 U.S. at 590.

excluded because they lack a reliable basis. Specifically, BSC argues that Dr. Shull reached opinions on the improper design of the Uphold without having first considered BSC's design protocols. Therefore, in BSC's view, Dr. Shull cannot opine on (1) the Uphold's "departure" from traditional surgeries, (2) BSC's failure to "follow its own internal protocols," or (3) BSC's lack of due diligence in the design and development of the Uphold. (BSC's Mot. to Limit the Ops. & Test. of Bobby L. Shull, M.D. & Mem. in Supp. ("BSC's Mot. re: Shull") [Docket 42], at 7). In response, the plaintiff contends that Dr. Shull's opinions regarding the design of the Uphold, while perhaps not based on BSC's design protocols, have a reliable foundation because he considered other sources, such as literature, other BSC internal documents, and his "extensive clinical experience." (Pl.'s Opp'n to BSC's Mot. to Limit the Ops. & Test. of Bobby L. Shull, M.D. & Mem. in Supp. ("Resp. re: Shull") [Docket 77], at 9).

Reliance on literature and experience is not dispositive here because the court must also ensure that the expert has "reliably applied" his methodology "to the facts of the case," Fed. R. Evid. 702, with "the same level of intellectual rigor that characterizes the practice of an expert in [that] field," *see Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). In this vein, Dr. Shull's opinion cannot survive. Dr. Shull admitted that he has never "seen any standard operating procedures" for BSC's medical device development, (Ex. C, Shull Dep. [Docket 77-3], at 256:23–257:8), nor has he seen Boston Scientific's design protocols, (*id.* at 255:18–23). Consequently, he has not reasonably applied the principles learned through his experience and the literature to the facts of this case. Furthermore, what he has seen—a handful of informal, disjointed emails between corporate representatives—is not something that a medical expert like Dr. Shull would usually consider in any context other than litigation.

Put simply, regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way. Therefore, these three opinions (listed as opinions 2, 11, and 12 in Dr. Shull's expert report) are **EXCLUDED**, along with any other opinions concerning BSC's design protocols.[9]

2. Opinions on Product Testing

BSC also challenges Dr. Shull's opinions concerning the testing performed on the Uphold, again claiming that Dr. Shull lacks the qualifications necessary to opine on this issue. In response, the plaintiff points to Dr. Shull's extended career as a pelvic floor surgeon. Experience as a surgeon alone, however, does not translate into experience with or knowledge about the appropriate testing a medical device manufacturer should undertake when preparing a product for the market. *See, e.g., Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *17 (S.D. W. Va. July 8, 2014) (excluding the opinions of Drs. Blaivas and Rosenzweig on the topic of medical device premarket testing because their work as urogynecologists and urologists does not give them knowledge on product testing). And there is no indication in Dr. Shull's expert report or otherwise that he has additional experience with product testing or clinical trials that sets him apart from the average pelvic surgeon on this particular matter. Accordingly, because Dr. Shull has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Federal Rule of Evidence 702 and cannot be admitted. *See* Fed. R. Evid. 702 (stating that an

[9] Because I find these opinions unreliable, I do not consider Dr. Shull's qualifications in the area of product design. *See* Fed. R. Evid. 702 (requiring an expert witness to be "qualified as an expert" *and* to base his testimony on "reliable principles and methods").

expert must be qualified . . . by knowledge, skill, experience, training, or education"). Any opinion concerning BSC's product testing, or lack thereof, is **EXCLUDED**.

3. Opinions on Product Labels

Next, BSC asserts that Dr. Shull is not qualified to opine on the adequacy of the Uphold's DFU, and even if he was qualified, his opinion on this issue lacks a reliable basis. With respect to Dr. Shull's qualifications, BSC states that Dr. Shull "is not an expert in the regulations or standards that govern [DFUs]; he has never advised a company on a DFU; he is unfamiliar with the industry process governing [DFUs]; and he has not even performed a literature search relating to DFUs." (BSC's Mot. re: Shull [Docket 42], at 9). The plaintiff, on the other hand, contends that Dr. Shull will not testify on "*how* BSC *developed* the warning" in the DFU, nor will he opine on the "regulatory requirements or the method or process that is used to develop and approve warnings." (Resp. re: Shull [Docket 77], at 10). Rather, the plaintiff offers Dr. Shull to opine on the completeness and accuracy of the Uphold warnings from a clinical perspective.

Although I agree with BSC that Dr. Shull is unqualified to opine on regulatory requirements and whether the Uphold labels and warnings satisfy those requirements, the plaintiff has confirmed that Dr. Shull's testimony will not touch on these issues. Instead, Dr. Shull will testify about the risks he perceives that the Uphold poses to patients, and he will opine that that the Uphold DFU did not convey these risks to physicians. A urogynecologist like Dr. Shull is qualified to make this comparison. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, as qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's DFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are

fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . .” (internal quotations and brackets omitted)). I also find that Dr. Shull’s forty years of experience, along with his evaluation of medical literature, (*see* Ex. A, Shull Report [Docket 43-1], at 4–7 (discussing existing literature on mesh complications)), forms a reliable basis for this testimony. *Kumho Tire Co.*, 526 U.S at 156 (stating that “an expert might draw a conclusion from a set of observations based on extensive and specialized experience”).

BSC’s remaining arguments against Dr. Shull’s labeling opinions go to credibility, not admissibility, and are better suited for cross-examination. Therefore, to the extent that Dr. Shull’s opinions on product labeling fit within the comparison described above, they are not excluded at this time. BSC’s motion on this issue is **DENIED**.

4. Opinion About the MSDS for Polypropylene Resin

Finally, BSC challenges “Dr. Shull’s opinion that he found no evidence BSC inquired into the scientific validity or basis of the MSDS” on the grounds that it is unreliable. (BSC’s Mot. re: Shull [Docket 42], at 14). To survive *Daubert*, an expert opinion must not be based on “belief or speculation.” *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). Here, Dr. Shull attempts to opine that because he did not find any evidence suggesting BSC inquired into the MSDS, none exists. Such a speculative leap is improper for expert testimony. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”). Therefore, this opinion is **EXCLUDED**.

BSC’s Motion to Limit the Opinions and Testimony of Bobby L. Shull, M.D. [Docket 42] is accordingly **GRANTED in part** and **DENIED in part**.

F. Jimmy W. Mays, Ph.D.

Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee who offers general causation opinions on the following issues: (1) the chemical structure and properties of polypropylene; (2) degradation of polypropylene by thermo-oxidative processes and in vivo; and (3) the effect of in vivo degradation on the polypropylene implant. Dr. Mays's opinions are based upon his experience, knowledge, and references to scientific literature. Additionally, Dr. Mays tested the chemical and thermal properties of seven BSC pelvic repair meshes, including the Uphold, and compared the results to four commercial isotactic polypropylene resins. Specifically, BSC takes issue with Dr. Mays's thermogravimetric analysis ("TGA"), which is a common method used for studying the thermo-oxidative stability of polymers.[10]

BSC seeks to exclude Dr. Mays's opinions based on his TGA because they are unreliable and irrelevant. By way of background, Dr. Mays performed TGA on seven exemplars in the air and compared their thermo-oxidative stability to that of four commercial polypropylene resins, all of which were stabilized with anti-oxidants. (Ex. B, Mays Report [Docket 43-2], at 17). Dr. Mays also removed the anti-oxidants from one Pinnacle exemplar to examine how the mesh degraded without stabilization. (*Id.*). Dr. Mays's results showed that all of the resins degraded in a similar manner. (*Id.*). Specifically, the specimens started to degrade around 230–250 degrees Celsius and nearly completely degraded at 400 degrees Celsius. (*Id.*). Dr. Mays noted that the Lynx product showed slightly better thermal stability than the others. (*Id.*). Based on this testing, Dr. Mays concludes that anti-oxidant stabilizers delay thermo-oxidative degradation, but do not

[10] As an initial matter, BSC attempts to incorporate by reference its *Daubert* objections to Dr. Mays's general causation opinions offered in *Sanchez v. Boston Scientific Corp.* BSC does not inform the court what these objections are or attach the *Sanchez* motion. Further, the expert report offered in *Sanchez* was authored by both Dr. Mays and Dr. Gido and is not identical to the report offered in the present case. Accordingly, I will not address the objections made in *Sanchez* and instead rule solely on the issues currently before me.

eliminate it; therefore, polypropylene will always degrade in an oxidative environment like the human body. (*Id.* at 43).

First, BSC argues that Dr. Mays's opinions should be excluded because his TGA did not replicate the in vivo environment. Specifically, BSC points out that Dr. Mays's TGA was conducted at temperatures well over 200 degrees Celsius when the human body is only approximately 37 degrees Celsius. (*See* BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Jimmy W. Mays, Ph.D. ("BSC's Mem. re: Mays") [Docket 43], at 7 ("TGA merely demonstrates that if you subject a plastic to a high enough temperature in air, it will degrade.")). In response, the plaintiff explains that TGA is "not intended to mimic the in vivo environment," but instead "is used as a model and provides predictive information that is particularly useful for product lifetime assessments." (Pl.'s Mem. in Opp'n to Def.'s Mot. to Exclude the Ops. & Test. of Pl.'s Expert [Docket 73], at 7).

Dr. Mays connects the TGA results to his ultimate conclusions regarding BSC's products in two places in his expert report:

> It should be noted that in the TGA experiments increasing temperature of the polypropylene in the presence of oxygen leads to degradation, which can be delayed but not eliminated by the presence of an anti-oxidant stabilizer packing. Polypropylene degradation also occurs isothermally inside the body. Here, too, polymer degradation may be slowed but not eliminated by the use of antioxidants.
> . . .
> Note that polypropylene always undergoes thermo-oxidative degradation in these experiments; the effect of anti-oxidant is only to delay the process. Likewise, the degradation of polypropylene exposed to an oxidative environment, such as the human body, can be delayed but not prevented through use of anti-oxidants.

(Ex. B, Mays Report [Docket 43-2], at 32, 43). The problem with these conclusions is one of fit. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). Dr. Mays produced certain results while testing polypropylene at very high temperatures. He then somehow concludes that the same results will

occur inside the human body at much lower temperatures, without providing any explanation or support for his opinion. "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Id.* at 591–92. Here, Dr. Mays has failed to connect his TGA results to the pertinent inquiry, which is whether the Uphold degrades inside the human body. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 44] is **GRANTED**, and Dr. Mays's general causation opinions based on his TGA are **EXCLUDED**.[11]

G. Russell Dunn, Ph.D.

Dr. Dunn is a registered professional engineer and the president and founder of Polymer Chemical Technologies, LLC, a company which focuses on process and product design issues, process and product safety, and polymer product analysis. Broadly, Dr. Dunn opines that BSC mesh devices are defective because the polypropylene mesh used in these devices undergoes oxidative degradation. BSC contends that Dr. Dunn is unqualified to opine on polypropylene pelvic mesh devices and that the testing he conducted is unreliable.

First, BSC argues that Dr. Dunn is not qualified to offer opinions concerning the design, risk management, or manufacture of polypropylene mesh devices. In support of this argument, BSC highlights Dr. Dunn's lack of experience with medical devices. In response, the plaintiff first notes that this court rejected certain *Daubert* objections to Dr. Dunn in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 710–11 (S.D. W. Va. 2014). However, Ethicon did not object to Dr. Dunn's qualifications in *Huskey*, as BSC has done here. The plaintiff also contends that the principles Dr. Dunn relies on are not specific to any kind of product but instead apply to the development of polymer products generally, which includes the development of medical devices.

[11] By excluding all of Dr. Mays's TGA opinions as irrelevant, I need not address BSC's arguments regarding the anti-oxidant removal process. (*See* BSC's Mem. re: Mays [Docket 43], at 8–9).

"The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas." *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) (finding an expert who is a mechanical engineer "not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering" and listing numerous cases with similar findings). "Although Rule 702 does not require [Dr. Dunn] to be 'precisely informed about all details of the issue raised in order to offer an opinion,' *Lorillard*, 878 F.2d at 799 (citations omitted), it also does not provide an open forum for expert testimony that will not assist the trier of fact." *Wright v. Brown*, 993 F.2d 1541, *2 (4th Cir. 1993) (unpublished table decision).

BSC cites to various admissions in Dr. Dunn's deposition evidencing his complete lack of experience with medical devices outside of litigation. (*See* BSC's Mot. to Exclude the Ops. & Test. of Russell Dunn, Ph.D. & Mem. of Law in Supp. ("BSC's Mot. re: Dunn") [Docket 46], at 5–6). For example, Dr. Dunn's company, Polymer Chemical Technologies, LLC, has been involved in over 200 projects focusing on polymer product design; however, none of these projects has involved a medical device. (*See* Ex. B, Dunn Dep. [Docket 46-1], at 10:12–15). Dr. Dunn also teaches five different chemical engineering courses at Vanderbilt University; however, he has never taught a course specific to medical devices or polypropylene. (*See id.* at 12:14–13:6). Similarly, Dr. Dunn states that he has a "tremendous amount of experience" assessing risk through Failure Mode and Effects Analysis ("FMEA"), but then admits that he has "never been involved in developing an FMEA for a medical device." (*Id.* at 273:8–25.). Finally, Dr. Dunn has authored many publications throughout his career; however, not one of these publications examines medical devices or how polypropylene behaves as part of a medical device. (*See id.* at 99:13–20).

All of Dr. Dunn's opinions are premised on his belief that the polypropylene mesh in BSC's devices will undergo oxidative degradation in the body, yet Dr. Dunn admits that he is not an expert in biomaterials or biocompatibility, and that he is not qualified to opine on the way polypropylene may affect the body physiologically. (*See id.* at 24:17–18, 152:12–14, 153:15–17). Even if Dr. Dunn relies on general engineering principles that apply to polymer products across the board, the opinions set forth in his expert report are clearly outside the scope of basic engineering. *See Shreve*, 166 F. Supp. 2d at 392 ("Unless he is to testify only to general engineering principles that any mechanical engineer would know, the engineer must possess some special skill, knowledge or experience, concerning the particular issue before the court." (quotation marks and citation omitted)). Unable to draw on some special skill, knowledge, or experience related to medical devices, Dr. Dunn's opinions, including those based on his testing of BSC products, will not be helpful to the trier of fact as required by Federal Rule of Evidence 702. Furthermore, Dr. Dunn's testing lacks sufficient indicia of reliability because he failed to follow a written protocol or utilize a sufficiently large sample size. (BSC's Mot. re: Dunn [Docket 46], at 9-13); *see also Daubert*, 509 U.S. at 594 (stating "the court ordinarily should consider the known or potential rate of error"). I find that Dr. Dunn does not have the requisite skill, knowledge, training, education, or experience to qualify as an expert in this case, and his opinions are unreliable, and therefore, **EXCLUDED**. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 46] is **GRANTED**.

H. Bruce Rosenzweig, M.D.

Dr. Bruce Rosenzweig is a urogynecologist and a professor of obstetrics and gynecology in Chicago, Illinois. The plaintiff primarily offers Dr. Rosenzweig as an expert witness on specific causation for Ms. Carlson. (*See generally* Ex. C, Rosenzweig Report [Docket 81-3]). In

addition, Dr. Rosenzweig has served a general report about the design and labeling of SUI products.[12] BSC attacks these opinions as unreliable. I address BSC's objections below.

1. General Causation Opinions

In his expert report concerning Ms. Carlson, Dr. Rosenzweig opines "[t]he Uphold design is flawed as set out in the general report." (*Id.* at 5). He also states, "[a]s discussed in my general liability report, Boston Scientific failed to include significant adverse events and risks in its IFU for the device . . . ." (*Id.* at 7). BSC asserts that to the extent these opinions intend to incorporate Dr. Rosenzweig's general report, it should be excluded. According to BSC, Dr. Rosenzweig's general report only discusses SUI products—specifically the Advantage Sling, Advantage Fit Sling, and Lynx Sling—and does not mention the Uphold or any other POP product. (*See* BSC's Mot. to Exclude the Test of Dr. Bruce Rosenzweig, M.D. & Mem. in Supp. ("BSC's Mot. re: Rosenzweig") [Docket 49], at 4 (quoting Dr. Rosenzweig's general report)). Therefore, BSC argues, Dr. Rosenzweig should not be able to "bootstrap" these SUI-specific opinions to cases involving POP products without additional explanation. (*Id.* at 5).

I agree. Federal Rule of Evidence 702 limits expert opinion testimony to that which "will help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. In other words, the expert's opinion must have "a valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591–92. Here, I find that Dr. Rosenzweig's general report—which does not mention the Uphold and instead proffers only SUI-specific opinions—lacks the requisite connection to the POP device at issue in this case.

First, Dr. Rosenzweig's general report focuses entirely on the use of Advantage mesh in SUI products. The Uphold, however, is made of a different mesh material called Polyform mesh.

[12] Neither party has attached this general report to its briefing, and so I must rely on the parties' representations of the report in my analysis.

Dr. Rosenzweig never mentions Polyform mesh, nor does he explain how his opinions on Advantage mesh could also apply to Polyform mesh, thereby failing to establish a discernible link between the opinions contained in his general report and the product implanted in Ms. Carlson. Second, although Dr. Rosenzweig specifically opines on the Uphold IFU and its alleged deficiencies in his report on causation for Ms. Carlson, (*see* Rosenzweig Report [Docket 81-3], at 7), he provides no bases for these opinions and simply refers to his general report. His general report, however, only considers the IFU for SUI products, which differs in form and substance from the IFU for POP products like the Uphold. Therefore, his general report cannot help the jury evaluate the warnings contained in the Uphold's IFU. In short, Dr. Rosenzweig's SUI-specific report cannot encompass the Uphold, absent further explanation accounting for the differences between the products.[13]

The plaintiff raises several arguments in an attempt to save Dr. Rosenzweig's general opinions on the design and labeling of the Uphold. First, the plaintiff argues that Dr. Rosenzweig was not relying on his own general report when he states that the Uphold design "is flawed as set out in the general report." Rather, he "incorporates by reference the general reports on each of these respective products." (Pl.'s Opp'n to BSC's Mot. to Exclude the Test. of Dr. Bruce Rosenzweig, M.D. & Mem. in Supp. ("Pl.'s Opp'n re: Rosenzweig") [Docket 81], at 5–6; *see also* Rosenzweig Report [Docket 81-3], at 34 (stating that he relied on "[a]ll general causation expert reports and documents relied upon served in Boston Scientific MDL 2326 as they relate to

[13] The plaintiff's insinuation that I have allowed otherwise in the past is incorrect. In *Tyree v. Boston Scientific*, an SUI case, I found Dr. Blaivas's reference to POP devices immaterial because he explained the applicability of his opinions to both synthetic slings and prolapse kits. *See Tyree*, __ F. Supp. 3d __, *48 (S.D. W. Va. 2014), *available at* 2014 WL 5320566 (reciting Dr. Blaivas's opinion that synthetic slings and prolapse kits cause serious and life-style altering complications) (internal quotation marks omitted). Here, however, Dr. Rosenzweig has expressly limited his opinions to "Wave I and II cases involving an Advantage Sling, an Advantage Fit Sling, or a Lynx Sling," never commenting on POP or POP devices. (BSC's Mot. re: Rosenzweig [Docket 49], at 4–5). Accordingly, I do not find *Tyree* dispositive.

Martha Carlson")). This argument has no effect on my disposition. An ambiguous reference to "all general causation expert reports" does not demonstrate reliance on "sufficient facts or data" as required for the admission of an expert opinion. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation—*i.e.*, "good grounds," based on what is known.").

Next, the plaintiff asserts that Dr. Rosenzweig developed his opinions on the Uphold's defective design from other sources, including "medical records," "scientific literature," and "clinical experience." (Pl.'s Opp'n re: Rosenzweig [Docket 81], at 6). Nowhere, however, does Dr. Rosenzweig identify these specific sources or explain how they substantiate his opinion on the alleged defectiveness of the Uphold. Instead, he refers back to his general report, which, as stated above, centers singularly on SUI products. Failure to apply a methodology to the facts of a case renders an expert's opinion inadmissible. *See* Fed. R. Evid. 702 (providing that an expert must "reliably apply[] the principles and methods to the facts of the case").

Finally, the plaintiff points to this court's previous decisions in which Dr. Rosenzweig's general causation opinions were not excluded. In those cases, Dr. Rosenzweig offered a general causation opinion on SUI devices, and the product at issue was a mid-urethral sling. *See Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *51 (S.D. W. Va. 2014), *available at* 2014 WL 5320566 (Obtryx); *Edwards v. Ethicon*, No. 2:12-cv-09972, 2014 WL 3361923, at *8–12 (S.D. W. Va. July 8, 2014) (TVT-O); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703–08 (S.D. W. Va. 2014) (TVT-O); *Lewis v. Ethicon*, No. 2:12-cv-4301, 2014 WL 186872, at *19 (S.D. W. Va. Jan. 15, 2014) (TVT). Here, Dr. Rosenzweig has invoked his SUI-specific report to opine that a POP product is defective, with no explanation of why his SUI-specific opinions can provide a reliable basis for POP-specific opinions. Accordingly, in light of the distinctions presented by

this case, I do not feel bound by my previous rulings.

Agreeing that Dr. Rosenzweig cannot, without explanation, extend his SUI-specific opinions to a POP case, and seeing no other reliable basis for his general opinions on the Uphold, I **GRANT** BSC's motion on this point. Dr. Rosenzweig's general causation opinions concerning the Uphold are therefore **EXCLUDED**.[14]

2. Specific Causation Opinions

Dr. Rosenzweig also provides a specific causation opinion for Ms. Carlson:

> It is my opinion to a reasonable degree of medical and scientific certainty, that the injuries suffered by Ms. Carlson . . . and the majority of her post-implant medical course are a direct result of implanting the Uphold device.

(Rosenzweig Report [Docket 81-3], at 5). BSC challenges this opinion on several grounds. First, BSC argues that Dr. Rosenzweig did not examine Ms. Carlson or speak to her treating physicians, and instead, he relied on the recorded examinations of other physicians. The Fourth Circuit Court of Appeals has held that "a physician may reach a reliable differential diagnosis without personally performing a physical examination." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). As such, Dr. Rosenzweig's failure to physically examine Ms. Carlson does not per se render his specific causation testimony unreliable, especially when he reached his opinions by studying the records of other physicians who did examine her. *See Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997), *as amended* (Dec. 12, 1997), ("[A] physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available.").

BSC next argues that Dr. Rosenzweig "repeatedly ignores and disregards the Plaintiff['s]

[14] In their briefing, both parties talk about a separate "Motion to Exclude Dr. Rosenzweig's General Causation Testimony as to the Advantage, Advantage Fit, and Lynx devices" that, according to BSC, was filed "concurrently with this motion." (BSC's Mot. re: Rosenzweig [Docket 49], at 1 n.1). No such motion has been filed on the docket. Thus, I do not address the parties' arguments pertaining to the independent reliability of Dr. Rosenzweig's general report.

medical records in forming his opinions." (BSC's Mot. re: Rosenzweig [Docket 49], at 8). Aside from this sweeping statement, however, BSC has presented no argument that Dr. Rosenzweig failed to adequately consider Ms. Carlson's medical records. Indeed, his report contains a thorough summary of Ms. Carlson's medical history, (*see* Rosenzweig Report [Docket 81-3], at 3–5 (providing a summary of Ms. Carlson's medical history from 2010, when she underwent implant surgery, to November 27, 2012)), and a list of medical records that he referred to in reaching his specific causation opinion, (*see id.* at 34 (listing ten sets of medical records that Dr. Rosenzweig relied upon in reaching his opinions)). Therefore, I find BSC's argument unpersuasive, and I **DENY** its motion to exclude with respect to Dr. Rosenzweig's specific causation opinion.

For the above reasons, BSC's Motion to Exclude the Testimony of Dr. Bruce Rosenzweig, M.D. [Docket 49] is **GRANTED in part** and **DENIED in part**.

I. Peggy Pence, Ph.D.

Dr. Pence works as a clinical and regulatory consultant, providing "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the [FDA]." (Ex. B., Pence Report (Nov. 10, 2014) [Docket 50-2], at 1).[15] During her career, she has accumulated knowledge about and experience with the testing requirements for medical devices; the development and content of product labeling; and the procedures necessary to comply with regulatory and industry standards, including those set forth by the FDA. (*See id.* at 1–5 (listing credentials and experiences)). In this

[15] Dr. Pence has submitted two expert reports, one focused on SUI products, (Ex. A, Pence Report (Dec. 9, 2013) [Docket 50-1]), and the other focused on POP products, (Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2]). The opinions appear to be the same in both reports, and the parties' briefings primarily refer to the most recent version. I follow suit and cite to the November 10, 2014 Report unless the arguments address an opinion stated only in the December 9, 2013 Report.

matter, Dr. Pence offers four opinions: (1) BSC did not conduct adequate testing of its products prior to placing them on the market; (2) the products were inadequately labeled; (3) patients could not adequately consent to the surgical implantation of the products due to the misbranding; and (4) BSC failed to meet the postmarket vigilance standard of care for these products.

Although I have considered these opinions before, Dr. Pence has since updated her expert report, and, in response, BSC has refined and reevaluated its objections. Therefore, turning to these objections, I am informed—though not bound—by my previous findings.

1. Dr. Pence's Qualifications

I first address BSC's argument that this court should exclude Dr. Pence's opinions because she lacks the qualifications necessary to make them. BSC maintains that Dr. Pence's work as a researcher and consultant on the development of medical products does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. In BSC's view, without a medical degree and without experience in the development of polypropylene mesh, Dr. Pence's opinions on BSC's medical devices cannot withstand *Daubert*.

I disagree. The absence of a medical degree on Dr. Pence's curriculum vitae does not call into doubt Dr. Pence's demonstrated knowledge about and experience with medical devices like those at issue. Dr. Pence has over forty years of experience in the research and development of medical devices. (Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 1). Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, I find that Dr. Pence is qualified to render the opinions set forth in her expert report, including her opinions about the safety and efficacy of mesh products and the sufficiency of BSC's product branding. Having found that Dr. Pence is

qualified to offer these opinions, I turn to whether her opinions are relevant and reliable.

2. General Objections

I begin by addressing two objections that BSC raises multiple times throughout its motion, all related to the reliability of the authoritative sources underlying Dr. Pence's opinions, which include a 2006 study by the French National Authority for Health ("HAS"), the recommendations of the National Institute for Health and Care Excellence ("NICE"), and the various guidance documents drafted by the Global Harmonization Task Force ("GHTF").[16] First, BSC argues that because these studies set forth *recommendations* rather than *requirements*, they cannot serve as a reliable basis for Dr. Pence's opinions. BSC, however, has not cited any case suggesting that the binding effect of industry standards dictates their reliability. Indeed, the Seventh Circuit Court of Appeals has suggested the opposite:

> [T]he relevant question for admissibility purposes is not whether the [] guidelines are controlling in the sense of an industry code, or even how persuasive they are. It is only whether consulting them is a methodologically sound practice on which to base an expert opinion in the context of this case.

Lees v. Carthage Coll., 714 F.3d 516, 525 (7th Cir. 2013). Accordingly, I give no import to the non-binding nature of the HAS, NICE, and GHTF recommendations in my *Daubert* analysis and instead focus on whether Dr. Pence's reliance on these sources constitutes a "methodologically sound practice."[17]

[16] The GHTF, which was conceived in 1992 and replaced by the International Medical Device Regulators Forum ("IMDRF") in 2011, represented a "partnership between regulatory authorities and regulated industry" and sought to "achieve greater uniformity between national medical device regulatory systems." (Ex. F, IMDRF, *GHTF Archive* [Docket 50-5], at 1). The European Union, United States, Canada, Australia, and Japan were the founding members, and these entities, as well as Brazil, China, Japan, and Russia, currently form the Management Committee of the IMDRF. (*Id.*). Dr. Pence relies on several GHTF "Final Documents" in reaching her opinions. (Ex. H, Pence Report (Nov. 10, 2014) [Docket 50-5], at Ex. 1).

[17] That said, because the guidelines that Dr. Pence relies upon are merely recommendations, Dr. Pence is prohibited from expressing to the jury that BSC was "required" to do anything under these standards, which she comes close to doing in her expert report. (*See, e.g.*, Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 42 ("Premarket Clinical Data Required")).

BSC also attempts to equate GHTF standards with FDA regulations and asserts that like FDA regulations, admission of GHTF standards, which have "regulatory purpose, history, and focus," could confuse and mislead the jury. (BSC's Mot. to Exclude the Ops. & Test. of Peggy Pence, Ph.D., & Mem. in Supp. ("BSC's Mot. re: Pence") [Docket 50], at 10). Thus, BSC argues that I should exclude Dr. Pence's opinions to the extent they rely on GHTF standards, as I have done with opinions that rely on the FDA. This argument misunderstands my concern with introducing FDA evidence. If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement. Such a perception of the product is erroneous, given that the product was cleared for market through the FDA's 510(k) process, which "does not in any way denote official approval of the device." 21 C.F.R. § 807.97 (2012). GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of the GHTF, *see generally* IMDRF, *GHTF organisational structure*, http://www.imdrf.org/ghtf/ghtf-structure.asp (last visited Apr. 7, 2015), that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA. Accordingly, I find BSC's argument without merit.

Having disposed of these issues, I now address BSC's arguments with respect to Dr. Pence's opinions on premarket testing, product labeling, and post-market vigilance.

3. Dr. Pence's Opinions on Appropriate Premarket Testing

In her report, Dr. Pence opines:

> BSC should have performed adequate preclinical and clinical testing of the [products] prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the standard of care required of a reasonably prudent medical device manufacturer.

(Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 52). In *Sanchez v. Boston Scientific Corp.*, I found this opinion reliable because Dr. Pence was able to support it with "multiple sources that stress the importance of running clinical trials before incorporating mesh materials into a surgical product," namely the HAS study and the NICE recommendations. No. 2:12-cv-05762, 2014 WL 4851989, at *34 (S.D. W. Va. Sept. 29, 2014). Here, Dr. Pence again relies on these studies, as well as GHTF standards, to support her opinion that BSC did not conduct appropriate premarket clinical trials.

Generally, BSC contends that none of the studies support Dr. Pence's opinion that BSC should have performed premarket clinical trials. My review of the exhibits, however, indicates that several guidance documents supply a basis for this opinion. For example, the GHTF's *Clinical Evaluation*, which Dr. Pence expanded on during her deposition, (Ex. G, Pence Dep. [Docket 50-5], at 192:2–197:19), states that prior to placing a device on the market, a manufacturer "must have demonstrated through the use of appropriate conformity assessment procedures that the device complies with the Essential Principles of Safety and Performance of Medical Devices," and part of this process involves analyzing—and sometimes generating—premarket clinical data. (Ex. I, GHTF, *Clinical Evaluation* 11 (May 8, 2007) [Docket 50-5] (illustrating that if the clinical evidence is lacking, a manufacturer should "generate new or additional clinical data")). Another GHTF guidance document states that "[a]t a minimum, tests should be conducted on samples from the finished, sterilized (when supplied sterile) device." (Ex. H, Pence Report (Nov. 10, 2014) Ex. 1: Applicable Industry Standards ¶ IV [Docket 50-5] (quoting GHTF, *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles* § 11 (Feb. 21, 2008))). Additionally, although the NICE and HAS studies are not as explicit as the GHTF documents, they both emphasize the importance of clinical trials

in assessing a product's safety for surgical use. (*See* Ex. B, HAS, *Evaluation of Mesh Implants Installed Through the Vaginal Approach in the Treatment of Genital Prolapse* 7 (Nov. 2006) [Docket 97-2] (emphasizing to surgeons "the necessity of using material validated by clinical trials"); Ex. D, NICE, *Surgical Repair of Vaginal Wall Prolapse Using Mesh* ¶ 1.1 [Docket 97-4] ("[T]his procedure should only be used with special arrangements for clinical governance, consent and audit or research.")).

Furthermore, all of these documents carry the indicia of reliability set forth by *Daubert*: the conclusions were reached after documented and validated testing; the results were published; and the testing was conducted through a defined methodology described in each paper. *See United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (listing the factors a court might consider when reviewing the reliability of expert testimony under *Daubert*). Therefore, I find Dr. Pence's consultation of these sources in reaching her opinion both justified and reliable.

Next, BSC argues that Dr. Pence's report lacks a "discussion of the [GHTF] standard itself" and "how Dr. Pence's application of that standard led her to form the opinions contained in her report." (BSC's Reply Mem. in Supp. of Its Mot. to Exclude the Ops. & Test. of Peggy Pence, Ph.D. [Docket 97], at 8). Dr. Pence's deposition testimony convinces me otherwise:

> . . . I looked at the product, what was known or not known with similar products, what was known historically, what they had done historically in terms of any types of testing, what they did or did not do in terms of testing to move forward and market these products, [] the same type of analysis and methodology I apply, as I said, with my product development consulting[. B]ased on that information[, I found] that they failed in establishing a favorable benefit-risk ratio because they did not do the appropriate testing and based on the information available to them, they did not have an adequate label to appropriately advise doctors of the information they needed to know . . . . [GTHF] guidance documents state that the products must meet the essential principles of safety and performance. The product must perform as intended to have a . . . favorable benefit-risk ratio. So they needed to do the appropriate testing to establish that.

(Ex. A, Pence Dep. [Docket 82-1], at 294:15–295:16). From this testimony, I find that Dr. Pence

has satisfactorily applied the GTHF standards, namely, *Clinical Evaluation* and *Essential Principles of Safety and Performance of Medical Devices*, to the facts of this case. Fed. R. Evid. 702 (providing that the court must ensure that the expert "has reliably applied the principles and methods to the facts of the case").

BSC's remaining arguments go to the weight of Dr. Pence's testimony, not its reliability, and are therefore better suited for cross-examination. In conclusion, I **DENY** BSC's motion to exclude Dr. Pence's opinion on premarket clinical testing.

4. Dr. Pence's Opinions on the Adequacy of BSC's Product Labels

Dr. Pence proffers two opinions regarding the labeling of BSC's products. First, she states that "BSC marketed [the Uphold] without adequate directions for use, notably, without adequate warnings, precautions, and information for implanting surgeons and patients about the extent and likelihood of potential risks, the difficulty of mesh removal and associated morbidity should mesh removal be required, and the potential permanency and life-altering implications of certain risks of mesh removal." (Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 72). Second, she states that "patients implanted with the [Uphold] were prevented from being adequately consented and giving fully informed consent as a result of BSC's inadequate professional and patient labeling." (*Id.* at 73). She then offers a list of warnings and risks that she believes should have been included in the products' DFU and patient brochures. (*Id.* at 67, 71).

BSC asserts that to the extent these opinions relate to BSC's deviation from the branding requirements of the Food, Drug, and Cosmetic Act ("FDCA"), they should be excluded. I agree. As I have held several times in the course of these MDLs, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about the state tort claims than enlightenment. The jury might think that the FDA regulations *govern* warning requirements in North Carolina, whereas Dr. Pence is actually using the FDA

regulations as a *model* for the contents of labeling material. *Daubert* advises courts to keep in mind the other rules of evidence when evaluating expert testimony, 509 U.S. at 595 ("Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules . . . ."), and applying Federal Rule of Evidence 403, I find that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion. *See* Fed. R. Evid. 403 (permitting exclusion of relevant evidence if its probative value is substantially outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury). Furthermore, simply stating that BSC did not comply with FDA regulations is a legal conclusion, not an expert opinion. For these reasons, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim") (internal quotations omitted). Any opinions arising from Exhibit 1 from Dr. Pence's December 9, 2013 Report, (Ex. E, Pence Report (Dec. 9, 2013) Ex. 1: U.S. Statutory and Regulatory Framework [Docket 50-5]), are **EXCLUDED**.

This finding, however, does not result in the exclusion of Dr. Pence's opinion on product labeling altogether because, unlike previous cases, Dr. Pence has a second source of information that is unrelated to the FDA, the GHTF's *Label and Instructions for Use for Medical Devices*, which I must also consider in my analysis. The plaintiff contends that this guidance document serves as adequate and reliable support that is "separate and distinct from FDA and FDCA regulations," and so Dr. Pence's opinion on product labeling survives BSC's *Daubert* challenge. (Pl.'s Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Peggy Pence, Ph.D. ("Resp. re: Pence") [Docket 82], at 14). In response, BSC asserts that even with the GHTF document, Dr.

Pence still lacks support for several of her labeling opinions. Specifically, according to BSC, *Label and Instructions for Use for Medical Devices* does not purport that a label should contain "information on severity, frequency, and/or permanency of potential adverse events" or "the difficulty of mesh removal," as Dr. Pence opines in her expert report. (BSC's Mot. re: Pence [Docket 50], at 14). I agree. The GHTF document on product labels does not state—expressly or otherwise—that manufacturers should include the severity, frequency, and/or permanency of adverse event in a warning, nor does it state that a label should qualify the difficulty of removing the device. (*See* Ex. J, GHTF, *Label and Instructions for Use for Medical Devices* 8–12 (Sept. 16, 2011) [Docket 50-5] (listing labeling content for medical devices)). Furthermore, Dr. Pence does not explain how this document could be interpreted as such. Rather, when pressed on this topic, Dr. Pence admits that the GHTF guidance document does not "get[] to that level of specificity." (Ex. G, Pence Dep. [Docket 50-5], at 261:1–3). Seeing no non-FDA grounds for Dr. Pence's opinion that BSC should have included this particular information in its labels, I find it unreliable, and it is therefore **EXCLUDED**.[18]

With respect to Dr. Pence's remaining opinions on product labeling, BSC moves for exclusion because Dr. Pence never spoke to any physicians about this issue. An expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other "sufficient facts or data" to support her opinion. Fed. R. Evid. 702. Here, Dr. Pence considered the GHTF's *Label and Instructions for Use for Medical Devices*, the DFU, several BSC internal documents, and other medical and scientific literature. (Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 53–72). I find this collection of sources sufficient for the purposes of *Daubert*. BSC has ample grounds to cross-examine and impeach Dr. Pence at

[18] BSC raises this objection only to Dr. Pence's opinions that the label should have included information on the difficulty of mesh removal and the permanency, severity, and/or frequency of adverse events. My holding is therefore limited to these specific opinions as well.

trial regarding any perceived oversights in her analysis.

5. Opinion on Post-Market Vigilance

In her last opinion, Dr. Pence proffers that BSC "failed to effectively monitor and manage evolving risks with its surgical mesh products for SUI and POP repair and to take appropriate action to minimize risk." (Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 93). BSC argues that this opinion is not helpful to a jury because it is "premised on (1) [Dr. Pence's] review of the adverse events submitted to the FDA's MAUDE Database with respect to the devices at issue and (2) GHTF/IMDRF guidance documents." (BSC's Mot. re: Pence [Docket 50], at 16).

In arriving at these opinions, Dr. Pence exclusively considered data from the FDA's MAUDE database.[19] From the database, she compiled and analyzed the complaints and adverse event reports related to the Uphold and concluded that BSC "fail[ed] to report serious adverse events." (Ex. B, Pence Report (Nov. 10, 2014) [Docket 50-2], at 93). As I have previously explained, BSC's communication, or alleged lack thereof, with the FDA through the MAUDE database has "no bearing on whether BSC provided adequate warnings or whether its products were defective." *Sanchez*, 2014 WL 4851989, at *36. Any opinion based on data collected in the MAUDE database, which acts as an arm of the FDA, is not helpful to the jury and is therefore inadmissible. *See* Fed. R. Evid. 702 (stating that the expert's specialized knowledge must "help the trier of fact to understand the evidence or to determine a fact in issue").

The plaintiff retorts that in using the MAUDE database, Dr. Pence "does not proffer opinions about an FDCA or FDA violation" and instead "proffers opinions that establish

[19] "The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers." FDA, *MAUDE – Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1 (last updated Feb. 28, 2015).

negligence under state tort law." (Resp. re: Pence [Docket 82], at 15). How and to what end Dr. Pence uses the data is inapposite, however, because further investigation into the MAUDE database reveals that it is unreliable, at least for the purposes of *Daubert*. The MAUDE system is a "passive surveillance system" that does not account for the "potential submission of incomplete, inaccurate, untimely, unverified, or biased data." FDA, *MAUDE – Manufacturer and User Facility Device Experience*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#fn1 (last updated Feb. 28, 2015). As such, the data has not been reviewed for accuracy at all, let alone peer-reviewed, and the court has no way to determine the rate of error associated with Dr. Pence's use of it. In addition, given that FDA warns users that the data alone "cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices," *id.*, I can readily conclude that that application of the data to reach a scientific conclusion about a manufacturer's conduct is not generally accepted in the scientific or medical community. Because Dr. Pence's opinion on post-market vigilance appears to be entirely based on data (or lack of data) found in the MAUDE database, I find it unreliable. Without a reliable basis, Dr. Pence's opinion on BSC's inadequate post-market vigilance is **EXCLUDED**, and BSC's motion on this matter is **GRANTED**.

6. Final Caveat: Relevance

I notice that several of the standards that Dr. Pence relies on were not published until after the Uphold had entered the market on August 22, 2008. BSC's conduct cannot be measured against standards not existing at the time the Uphold was being manufactured and prepared for sale. *See Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1177–78 (4th Cir. 1997) ("[M]anufacturers are required to design products that meet prevailing safety standards *at the time the product is made*.") (emphasis added). Therefore, any testimony relying on standards

published after August 22, 2008, is irrelevant and not helpful to the jury. *See* Fed. R. Evid. 702 (limiting expert testimony to opinions that "will help the trier of fact to understand the evidence or determine a fact in issue"). As such, I **EXCLUDE** Dr. Pence's opinions derived solely from such sources. I trust in able counsel to tailor Dr. Pence's testimony accordingly.[20]

In sum, BSC's Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [Docket 50] is **GRANTED in part** and **DENIED in part**.[21]

J. Richard Trepeta, M.D.

Dr. Trepeta, among other things, is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. (*See* Ex. A, Trepeta Report [Docket 75-1], at 1–2). As part of his fellowship, he "establishes criteria and terminology for the diagnosis of vulvar and vaginal diseases." (*Id.* at 2). Dr. Trepeta also examines vulvar–vaginal pathology samples through his private practice. (*Id.*). In this case, the plaintiff offers Dr. Trepeta to testify as an expert witness on the general pathology of vaginal mesh implantation. (*See generally id.*). BSC moves to exclude his opinions on the grounds that Dr. Trepeta lacks the qualifications to make them and that his opinions lack a reliable basis.

I have reviewed Dr. Trepeta's opinion, as well as these objections to it, several times throughout the course of this MDL. *See Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–24 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *15–19 (S.D. W. Va. 2014), *available at* 2014 WL 5320566; *Eghnayem v.*

[20] This court will invoke similar limitations to Dr. Pence's testimony throughout these wave cases, depending on the device at issue and when it was placed on the market, which will, of course, lead to different testimony from Dr. Pence at each wave trial. In fact, in cases involving BSC's earlier products, this limitation might prevent Dr. Pence from testifying at all, given that many of the sources she relies on to reach her opinion on premarket testing were not promulgated until 2005 or later. Again, I depend on counsel to ensure that Dr. Pence does not render opinions based on standards that did not exist when the product at issue entered the market.

[21] BSC's objection to Dr. Pence's opinions on the alleged carcinogenicity of polypropylene, uncontested by the plaintiff, is **GRANTED**.

Boston Scientific Corp., __ F. Supp. 3d __, *5–9 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. The expert report and *Daubert* objections that were before the court in these previous cases are the same as those before the court today. (*See* Pl.'s Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Richard Trepeta, M.D. ("Resp. re: Trepeta") [Docket 75], at 4 (stating that Dr. Trepeta has not changed his Rule 26 report or his opinions since the *Eghnayem*, *Tyree*, and *Sanchez* rulings)). My holdings, therefore, are likewise the same.

1. Dr. Trepeta's Qualifications

To testify as an expert, a witness must be "qualified . . . by knowledge, skill, experience, training or education." Fed. R. Evid. 702. Although Dr. Trepeta has an impressive background in medicine, BSC argues that his medical training does not qualify him under Rule 702 to render the opinions he sets forth in his expert reports.

a. Properties of Polypropylene Mesh

First, BSC objects to Dr. Trepeta's opinion testimony on the properties of polypropylene mesh. In his general report, Dr. Trepeta opines about mesh degradation, mesh contraction, and mesh migration. He states that "[d]egradation occurs as either fragmentation of the mesh or oxidation [of the mesh] release[s] chemical components from the mesh into surrounding tissues," and "[m]esh contraction and shrinkage cause the mesh to be significantly decreased in its physical size." (Ex. A, Trepeta Report [Docket 75-1], at 5). BSC asserts that Dr. Trepeta is not qualified to put forth these opinions because he is not a material scientist, biochemist, or biomedical engineer. Furthermore, he has no training in polymer science or biomedical engineering and has not performed mechanical or chemical testing of mesh products.

In making this argument, however, BSC downplays Dr. Trepeta's knowledge, training, and experience as a clinical pathologist. In general, a clinical pathologist "will be knowledgeable

in the areas of chemistry, hematology, microbiology, . . . serology, immunology, and other special laboratory studies." 33 Am. Jur. *Trials* 467 § 17 (1986); *see also* Coll. of Am. Pathologists, *CAP Fact Sheet*, http://www.cap.org/apps/docs/laboratory_accreditation/international_cap_fact_sheet.pdf (last visited Apr. 3, 2015) ("[Clinical pathologists] are involved in a broad range of disciplines, including surgical pathology, cytopathology, . . . clinical chemistry, microbiology, immunopathology, and hematology."). Dr. Trepeta's thirty years of experience as a clinical pathologist therefore demonstrates sufficient knowledge to provide expert testimony about the chemistry and surgical pathology of materials like transvaginal mesh. Moreover, Dr. Trepeta has knowledge of and experience with pelvic mesh explants in particular, having examined fifty explant samples over the past five years. (Ex. A, Trepeta Report [Docket 75-1], at 2). Given Dr. Trepeta's knowledge and experience as an anatomical and clinical pathologist, I find him qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC's motion in this respect.

b. The Human Clinical Response to Polypropylene Mesh

Second, BSC objects to Dr. Trepeta's testimony on the human clinical response to mesh implants. Dr. Trepeta opines that the "human body's pathological response to implantation of polypropylene mesh as well as the inherent physical properties of the mesh cause permanent injuries resulting in distortion of the pelvic architecture, sexual dysfunction, persistent pain, scarring, and alteration of bowel and bladder function." (Ex. A, Trepeta Report [Docket 75-1], at 6). BSC contends that Dr. Trepeta is not qualified to present this opinion because Dr. Trepeta does not treat patients for these conditions and has limited familiarity with the symptoms of SUI and POP. In short, BSC argues that Dr. Trepeta is not a gynecologist, obstetrician, urogynecologist, or a surgeon, and as a result, Dr. Trepeta's opinions about the clinical response

to mesh should be excluded.

As I explained in *Sanchez*,

> Dr. Trepeta's extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through "clinical and pathologic correlation." (*See* [Trepeta Dep.] at 11:10–14). Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. (*See id.*). Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings "are well described in the published literature." (*Id.*). Dr. Trepeta's understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response.

2014 WL 4851989, at *20. Therefore, I **DENY** BSC's motion on this point.

2. The Reliability and Relevance of Dr. Trepeta's Opinions

As stated previously, an expert's opinion is admissible if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. BSC raises two objections to the reliability and relevancy of Dr. Trepeta's opinion testimony, and I address each of these objections below.

a. Reliability of Dr. Trepeta's Methodology

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion. First, Dr. Trepeta has studied over fifty mesh explant samples in his private practice. Dr. Trepeta received these samples from physicians about once a month over the past five years. (Ex. B, Trepeta Dep. [Docket 75-2], at 71:8–13). He examined these samples under a microscope, identified any abnormalities, and concluded that the samples presented injuries "consistent with the pathological process of tissue response and/or injury due to polypropylene." (Ex. A, Trepeta

Report [Docket 75-1], at 2). Second, Dr. Trepeta studied the medical literature on mesh implantation and determined that his pathological findings correspond with the published research on mesh erosion and exposure in the vaginal wall. (*Id.* at 2–3). Third, Dr. Trepeta reviewed twenty-four pathology reports that he received from the plaintiff's counsel and ascertained that "the pathology reports of excised Boston Scientific Products . . . are consistent" with the acute, sub-acute, and chronic categories of the disease process. (*Id.* at 4).

BSC's strongest objection to Dr. Trepeta's methodology focuses on this third source of information. BSC argues that the twenty-four pathology reports were unreliable because: they were "hand-picked by Plaintiffs' counsel"; Dr. Trepeta only relied on seventeen of the twenty-four reports; and Dr. Trepeta did not review the medical records of any of the probed patients. (BSC's Mot. to Exclude the Ops. & Test. of Richard Trepeta, M.D. & Mem. in Supp. [Docket 51], at 5–7). The plaintiff responds that these pathology reports only supplemented Dr. Trepeta's opinion and that the main thrust of Dr. Trepeta's opinion comes from his review of fifty mesh explants over the past five years and from his study of medical literature. Moreover, the plaintiff argues that BSC's chosen expert, Dr. Badylak, agreed that review of pathology reports of vaginal tissue taken from polypropylene explants is an accepted method for reaching a pathologic conclusion on tissue response to polypropylene. (Resp. re: Trepeta [Docket 75], at 4–5).

The fact that each side's pathologist accepts this practice suggests that it is accepted by the general community of pathologists. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . . ."). But Dr. Trepeta's review of the pathology reports still has a fatal deficiency in that it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. *See id.* (listing as a factor in evaluating an expert's opinion the "existence and maintenance of standards controlling

the technique's operation"). The plaintiff does not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. *See id.* (stating that the "court ordinarily should consider the potential rate of error"). I confronted a similar situation in *Lewis v. Ethicon, Inc.* and excluded the expert opinion on hand-selected explant samples because "[t]here are no assurances that [plaintiff's counsel] did not opportunistically choose samples while ignoring others that might have weakened or disproved [the expert's] theories." No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan 15, 2014). Here, I similarly have no way to ensure that the plaintiff's counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions. Accordingly, Dr. Trepeta's opinions derived from his review of the twenty-four pathology reports are **EXCLUDED**.

b. Litigation Driven

Finally, BSC argues Dr. Trepeta's opinions are unreliable because they are litigation driven. On the contrary, Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Ex. A, Trepeta Report [Docket 75-1], at 2; *see also* Ex. B, Trepeta Dep. [Docket 75-2], at 71:6–23 (explaining that over the past five years of his thirty-year practice, he has examined about fifty mesh explants that physicians had sent to him)). This work took place outside of this litigation. Thus, I find that Dr. Trepeta's opinions are not litigation-driven and **DENY** BSC's motion on this point.

In conclusion, Dr. Trepeta's general causation opinions are admitted, apart from his opinions based on the pathologic reports selected by the plaintiff's counsel for his review, which are excluded. Accordingly, BSC's Motion to Exclude the Opinions and Testimony of Dr. Trepeta [Docket 51] is **GRANTED in part** and **DENIED in part**.

K. Scott Guelcher, Ph.D.

Dr. Guelcher is a chemical engineer offered by the plaintiff to opine on how the human body responds to polypropylene once it is implanted and the reactions that occur on the surface of the implant. Broadly, BSC contends that Dr. Guelcher's opinions on oxidative degradation should be excluded because the testing he relies upon—testing completed by Dr. Dunn—is unreliable. As discussed more fully *supra*, because I **EXCLUDE** Dr. Dunn as an expert in this case, Dr. Guelcher's opinions—to the extent they are based on Dr. Dunn's testing—are likewise **EXCLUDED**. Therefore, BSC's Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 52] is **GRANTED**.

L. Vladimir Iakovlev, M.D.

Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. Dr. Iakovlev offers both general and specific causation opinions with regard to the body's response to mesh from a pathologic perspective. BSC argues that Dr. Iakovlev's general causation opinions should be excluded because he relies on specimens other than Ms. Carlson's. BSC also argues that Dr. Iakovlev's specific causation opinions should be excluded because he did not review the pathology for this particular plaintiff, Ms. Carlson.

1. General Causation

BSC contends that this court should "exclude Dr. Iakovlev's opinions on specimens other than each plaintiff's." (BSC's Mot. to Strike and Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. [Docket 56], at 4). Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. (*See* Ex. 2, Iakovlev Report [Docket 56-2], at 2, 5). However, Dr. Iakovlev provides no information on how the mesh

explants were chosen or prepared for examination. Dr. Iakovlev testified that plaintiff's counsel provided approximately 70% of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed. (Ex. B, Iakovlev Dep. [Docket 80-3], at 38:12–39:21). Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014). "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594).

In response, the plaintiff contends that Dr. Iakovlev's methodology is sound because it has been subjected to the publication and peer-review process. This past year, Dr. Iakovlev published two articles in peer reviewed journals about his mesh explant research. *See* Vladimir V. Iakovlev, et al., *Pathology of Explanted Transvaginal Meshes*, 8 Int'l J. Medical, Health, Biomedical and Pharmaceutical Engineering No. 9 (2014); Robert Bendavid, et al., *Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain*, 5 Int'l J. Clinical Med. 799, 799–810 (2014). However, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability," and is not dispositive. *Daubert*, 509 U.S. at 593–94. In his most recent deposition, Dr. Iakovlev does not explain how the explant samples were chosen and neither do these articles. Therefore, despite publication, the court's concerns with regard to the data pool remain. Likewise, upon review, I find the plaintiff's remaining arguments to be without merit. Accordingly, BSC's motion on this matter is **GRANTED**, and Dr. Iakovlev's general causation opinions based on his data pool are **EXCLUDED**.

2. Specific Causation

It is unclear whether Dr. Iakovlev intends to offer a specific causation opinion in this case because the court has not been provided with an expert report from Dr. Iakovlev specific to Ms. Carlson. Regardless, BSC's Exhibit 1 indicates that Ms. Carlson's case is one where Dr. Iakovlev did not review any pathology. (Ex. 1 [Docket 56-1], at 2). In *Eghnayem v. Boston Scientific Corp.*, I found Dr. Iakovlev's specific causation opinions reliable based on his "morphological differential diagnosis," which included an examination of the plaintiff's explanted mesh. __ F. Supp. 3d __, *46 (S.D. W. Va. 2014), *available at* 2014 WL 5461991. In this case, there is no evidence that Dr. Iakovlev examined Ms. Carlson's explanted mesh or performed a physical examination. Assuming Dr. Iakovlev seeks to offer specific causation opinions, such opinions are not sufficiently reliable under *Daubert* and are thus **EXCLUDED**.

In conclusion, BSC's Motion to Strike and Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 56] is **GRANTED**.

V. The Plaintiff's *Daubert* Motions

In this case, the plaintiff seeks to limit or exclude the expert opinions of Drs. Christine Brauer, Patrick Culligan, Roger Goldberg, Gary L. Winn, Stephen Spiegelberg, and Stephen F. Badylak.

A. Christine Brauer, Ph.D.

Dr. Brauer is the President of Brauer Device Consultants, LLC, where she provides consulting services to the medical device industry regarding FDA regulatory requirements. The plaintiff seeks to exclude both of Dr. Brauer's expert reports filed on November 21, 2014. The first report ("FDA report") focuses on the FDA regulatory requirements for surgical devices, and the second report ("supplemental report") focuses on industry standards that a manufacturer of a

medical device must meet. (*See* Ex. 2, Brauer Dep. [Docket 91-2], at 8:13–20). "Anticipating that the Court will adopt its prior rulings and exclude FDA evidence here," BSC does not contest the plaintiff's motion with regard to the FDA report. (BSC's Resp. in Opp'n to Pl.'s Mot. to Exclude or Limit the Test. of Expert Christine Brauer, Ph.D. [Docket 69], at 1). In *Sanchez v. Boston Scientific Corp.*, I ruled as follows:

> I have repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, at 753–56 (S.D. W. Va. 2014). Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. *See, e.g.*, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) ("The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.") (internal reference omitted); Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. July 1, 2013), [Docket 309], at 3–4 ("Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective . . . . Because the FDA 510(k) process does not go to whether the [mesh] products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues."); Mem. Op. & Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. June 27, 2013) [Docket 302], at 3–4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403); Mem. Op. & Order, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D. W. Va. May 12, 2014 [Docket 223], at 1 ("This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA's 510(k) process . . . In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to the safety and efficacy of medical devices and because of the potential to mislead and confuse the jury."). Accordingly, I **FIND** that Dr. Brauer's opinions should be excluded in their entirety.

No. 2:12-cv-05762, 2014 WL 4851989, at *36–37 (S.D. W. Va. Sept. 29, 2014). Accordingly, the plaintiff's motion with regard to Dr. Brauer's FDA report is **GRANTED**, and her opinions set forth in that report are **EXCLUDED**.

With regard to the supplemental report, the plaintiff contends that it "is nothing more that

[sic] her FDA Report under a different cloak." (Pl.'s Reply in Supp. of Pl.'s Mot. to Exclude or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 91], at 4). Therefore, in the plaintiff's view, Dr. Brauer's supplemental report should be excluded for the same reasons her FDA report was previously excluded, given that the two reports are "substantially identical." (Pl.'s Mot. & Mem. to Exclude or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket 44], at 2). I agree. Reading the two reports side by side, it appears that Dr. Brauer "supplemented" her report by removing references to the FDA and substituting the term "industry standard" instead. For example, in her supplemental report, Dr. Brauer states: "It is an industry standard for a manufacturer of certain new or modified medical devices to demonstrate that its new device is substantially equivalent to another legally marketed device, and is as safe and effective as other similar devices prior to marketing in this U.S." (Ex. 3, Brauer Report [Docket 69-1], at 4). This "industry standard" clearly describes the FDA 510(k) process, which Dr. Brauer admits in her deposition. (*See* Ex. 2, Brauer Dep. [Docket 91-2], at 43:7–18 ("Q: I'm talking about this one sentence . . . That's the 510(k) process; correct? A: That is the 510(k) process.")).

Also, Dr. Brauer states that medical devices are grouped into three categories, which she labels as "Low-Risk," "Moderate Complexity and Risk," and "Complex, High Risk." These "industry standard" categories perfectly align with the three regulatory classes established by the Medical Device Amendments, another fact Dr. Brauer admits. (*See id.* at 48:13-–9 ("Q: The low-risk medical devices are Class I devices. The moderate complexity and risk medical devices are Class II devices; correct? A: For most products, they probably would fit in that way, yes.")).

BSC contends that Dr. Brauer's industry standard opinions do not require presenting FDA evidence to the jury because the industry standards are broader than FDA regulations.

However, Dr. Brauer explains that FDA regulations are part of industry standards, and, therefore, any evidence with regard to industry standards would require reference to the FDA, whether it is disguised or not. (*See id.* at 34:13–23 ("A: When you do it with industry, you want to make sure that your regulatory requirements are met, but also that certain customer needs are met. So there's a little different of a slant, but it's still the primary same content. Q: So in both ways you're trying to comply with FDA regulations? A: In part. In both ways you're trying to comply with FDA regulations because that's part of it.")).

Furthermore, although she cites a few standards issued by the International Organization for Standardization ("ISO"), including ISO 13485, in her supplemental report, when asked about additional standards during her deposition, Dr. Brauer cannot recall any specific standards, other than ISO 13485. (*Id.* at 35:15–21). And when pressed on whether there is an ISO standard that requires manufacturers to submit adverse events to the FDA, Dr. Brauer is unable to articulate an identifiable ISO standard to support her premise. (*See id.* at 46:18–47:1 ("Q: It says that it's an industry standard to submit certain reports to adverse events to the FDA. A: That's correct. Q: So there's no actual standard that says that; correct? A: I don't believe it's that specifically stated in the ISO standard.")). Dr. Brauer's inability to identify an applicable standard renders her opinion unreliable. *See Lasorsa v. Showboard: The Mardi Gras Casino*, No. 07-4321, 2009 WL 2929234, at *5 (D.N.J. Sept. 9, 2009) ("Without a reliable, objective basis for [expert] testimony, stemming from identifiable industry standards, codes, publications or training, it must be precluded under Rule 702.")

Dr. Brauer's deposition testimony reveals that her true area of expertise is the regulatory field, which is why she was originally retained to write a regulatory report. (*See id.* at 12 ("I believe the first contact was regarding FDA regulation of medical devices.")); *see also Pension*

Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC, 691 F. Supp. 2d 448, 476 (S.D.N.Y. 2010) (finding an expert's opinions with regard to industry standards unreliable when not "ground[ed] in his knowledge of the custom and practice of the industry"). There is far too much overlap between Dr. Brauer's FDA report and supplemental report to avoid a regulatory mini-trial, which I have repeatedly and consistently held would confuse and mislead the jury. Accordingly, the plaintiff's Motion to Exclude or Limit the Testimony of Christine Brauer, Ph.D [Docket 44] is **GRANTED**, and Dr. Brauer's opinions are **EXCLUDED** in their entirety.

B. Patrick Culligan, M.D.

The plaintiff moves to exclude certain opinions and testimony of Patrick Culligan, M.D. Dr. Culligan is a urogynecologist. (Ex. B, Culligan Report [Docket 45-2], at 1). In his expert report, he offers nine opinions that relate to polypropylene POP repair products, traditional procedures to treat POP, the risks associated with pelvic surgeries and mesh, BSC's Uphold device, and the Uphold DFU. (*See id.* at 18–19). The plaintiff argues that his testimony should be limited on qualifications and reliability grounds.

1. Opinions Concerning Safety and Efficacy of Uphold

The plaintiff argues that Dr. Culligan's opinions concerning the safety and efficacy of the Uphold should be excluded because Dr. Culligan's method was unreliable.

First, the plaintiff challenges Dr. Culligan's opinion that the Uphold is safe and effective to treat POP. (*Id.* at 18). The plaintiff argues that Dr. Culligan admitted in his deposition that there are only four scientific studies addressing the Uphold. She also contends that Dr. Culligan may not reliably base his Uphold opinions on studies about other POP products because Dr. Culligan testified that he did not have detailed knowledge as to how these products compare. He additionally testified that there are no direct comparison studies concerning these products. (*See*

Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 301:14–302:9). Even so, I find Dr. Culligan's method to be reliable. As revealed by his expert report and his relied-upon list, (*see* Ex. B, Culligan Report [Docket 45-2], at Ex. B), Dr. Culligan based his opinions on scientific literature, including a published study that he conducted on the Uphold. If the plaintiff wishes to argue that his conclusions are not correct in light of his research, then she may do so on cross-examination.

Next, the plaintiff challenges Dr. Culligan's opinion that the Uphold is safer and more effective than traditional non-mesh POP procedures. (*Id.* at 18).[22] The plaintiff states that Dr. Culligan "admitted . . . [t]here are no studies that compare the safety of the Uphold device to the safety of non-mesh surgeries . . . [and] [t]here are no studies that compare the efficacy of the Uphold device to the efficacy of non-mesh surgeries[.]" (Mot. & Mem. in Supp. of Pl.'s Mot. to Exclude Certain Ops. & Test. of Dr. Patrick Culligan ("Pl.'s Mot. re: Culligan") [Docket 45], at 3–4). The deposition testimony that the plaintiff cites in support of this proposition is as follows:

> Q: Okay. Are there any RCTs comparing native tissue repairs to Uphold for safety?
>
> A: There are no studies of any sort I'm aware of where an outcome has recalled safety is [sic] one of the outcome measures. I think that that's a very broad topic, and -- and you couldn't design a study around, quote-unquote, safety as an outcome measure.
>
> . . .
>
> Q: . . . Are there any long-term RCTs that exist comparing native tissue repair to Uphold for efficacy?
>
> A: No.

(Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 294:4–13, 294:18–22). However, Dr. Culligan's method is not unreliable just because a direct comparison study does not exist

[22] BSC contends in its response that the plaintiff does not challenge this opinion. Upon my reading of the plaintiff's motion, I disagree.

between these treatments. Dr. Culligan, by way of his experience with the Uphold device and his review of the relevant scientific literature, may reliably form an opinion on how these procedures compare. (*See* Ex. B, Culligan Report [Docket 45-2], at Ex. B. (relied-upon list including scientific literature)). His method survives *Daubert* scrutiny.

The plaintiff's remaining arguments concerning the reliability of Dr. Culligan's safety and efficacy opinions are also unavailing. First, the plaintiff argues that Dr. Culligan may not reliably consider his personal experience in forming his opinions because Dr. Culligan could not testify as to exact statistics about his patients (i.e., how many patients he has implanted with an Uphold). However, such detail is not required under *Daubert* to opine as to the "*large-scale* safety and efficacy of the Uphold device[,]" as the plaintiff phrases it. (Pl.'s Mot. re: Culligan [Docket 45], at 4 (emphasis added)).[23]

Second, the plaintiff argues that Dr. Culligan failed to account for contrary literature in forming his opinions about the safety and efficacy of the Uphold. The plaintiff merely cites to the following deposition testimony in support:

> Q: Dr. Culligan, if Boston Scientific said internally that mesh shrinks, do you disagree with that?
>
> A: I've already disagreed with it. I think many people believe that. But I think that it's not been proven, and I simply choose not to believe it. I think it's a bit of a myth.

(Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 388:21–389:7) (objection omitted). I am satisfied that Dr. Culligan followed a reliable methodology in reaching his opinions on the safety and efficacy of the Uphold device, notwithstanding the plaintiff's citation to the above deposition

[23] At this point in her motion, the plaintiff also challenges an opinion that Dr. Culligan asserts at his deposition—that the complication rate in his patients implanted with the Uphold is 1%. Dr. Culligan testifies that he would not provide the basis for this opinion to the plaintiff's lawyers without first requesting legal advice on the matter. (*See* Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 249:1–18). However, this opinion is not within Dr. Culligan's report. (*See* Ex. B, Culligan Report [Docket 45-2], at 18–19). Thus, I must presume that Dr. Culligan does not plan to offer it at trial, and I need not assess the reliability of it.

testimony. Furthermore, I decline to address Dr. Culligan's opinion on shrinkage here. The plaintiff brings a separate challenge to such opinions, which is addressed below. Thus, the plaintiff's motion with respect to this matter is **DENIED**.

2. Opinions on Physical Properties of Polypropylene Mesh

Next, the plaintiff argues that Dr. Culligan's opinions on the physical properties of polypropylene mesh—including pore size, shrinkage, foreign body response, and degradation—are based on an unreliable method. (*See* Ex. B, Culligan Report [Docket 45-2], at 18–19). I agree. Although Dr. Culligan considered the scientific literature and his experience in forming these opinions, his deposition testimony reveals flaws in his method. In particular, his deposition testimony reveals that Dr. Culligan heavily relied upon his clinical experience in forming his opinions on pore size, shrinkage, foreign body response, and degradation, even though his experience with such topics is lacking.

For example, Dr. Culligan testified that he has never measured under a microscope the pore size of any Uphold or BSC polypropylene mesh product. (Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 71:18–72:6). Although Dr. Culligan testified that his "best support for [the contention that mesh does not shrink] . . . is [his] clinical experience[,]" he also testified that he has never measured patients' explants for shrinkage. (*Id.* at 349:9–14; 357:13–21). According to Dr. Culligan, he has not seen or felt shrinkage in his patients, and, thus, "mesh shrinkage . . . is simply not a clinical problem that [he] recognize[s.]" (*Id.* at 358:5–18).

Moreover, Dr. Culligan does not ask pathologists to examine his explants for chronic inflammation or foreign body response. (*Id.* at 311:22–312:4). He explains that he does not need to because "[t]hat's what [pathologists] do, that's their -- that's their job." (*Id.* at 312:16–24). He declines to ask pathologists to test his explants for degradation because "[he'd] be asking them to

look for something that [he] do[es]n't even believe happens." (*Id.* at 315:3–8). Dr. Culligan provides the following basis to supports his degradation opinions:

> A: In a -- in a clinically meaningful way, I do know how to assess for degradation, because I do it every time that I operate on a patient and do an explant. It's -- the properties of mesh are apparent to me, and -- when I'm removing a mesh, just like when I'm putting it in. And I don't -- the -- the clinical properties of the mesh are something I'm well aware of.

(*Id.* at 315:12-22). Dr. Culligan's inherent awareness of "the clinical properties of mesh" is not a reliable basis to form an expert opinion. (*Id.*). Thus, his method is unreliable under *Daubert*. The plaintiff's motion with respect to these opinions is **GRANTED**.

3. Opinions on Mesh Design

Next, the plaintiff contends that Dr. Culligan is not qualified to opine as to mesh design. I agree. Dr. Culligan testified at his deposition that he has not designed any POP products. (*Id.* at 111:19–21). The court is unpersuaded by BSC's argument that Dr. Culligan has sufficient experience with pelvic floor repair kits to opine as to the Uphold design. Dr. Culligan's opinions on this matter are **EXCLUDED**.

4. Opinions on DFU

The plaintiff also argues that Dr. Culligan is unqualified to opine as to the Uphold DFU. (*See* Ex. B, Culligan Report [Docket 45-2], at 18). I agree. Dr. Culligan has participated in drafting a DFU yet hired a regulatory consultant to assist him and check his work. (*See* Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 383:7–16). In prior cases, he testified as to his lack of expertise in this area. *See Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *68–69 (S.D. W. Va. 2014), *available at* 2014 WL 5320566. Just because Dr. Culligan now states that he has not given himself enough credit as to his qualifications in the past—specifically, that he was "literally just being too hard on [him]self"—is not sufficient for the court to deem him qualified

to opine as to this matter. (Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 82:20–21). BSC has not "come forward with evidence from which the court" can find Dr. Culligan qualified here. *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3 780, 783 (4th Cir. 1998). His opinions on the DFU are **EXCLUDED**.

5. Opinions on MSDS

The plaintiff next challenges Dr. Culligan's opinions concerning the MSDS. BSC concedes that Dr. Culligan will not offer opinions "regarding the meaning of statements contained in the Phillips Sumika Material Safety Data Sheet." (Mem. in Opp'n to Pl.'s Mot. to Limit the General Ops. & Test. of Patrick Culligan, M.D. ("BSC's Resp. re: Culligan") [Docket 67], at 4 n.12). Also, I decline to entertain the plaintiff's challenge to Dr. Culligan's other opinions concerning the MSDS. At Dr. Culligan's deposition, the parties agreed as to the parameters of his testimony on this matter. The parties agreed that Dr. Culligan could testify that "[he] didn't know what an MSDS sheet was and that 'he'd never consulted one." (Ex. C, Culligan Dep. (Jan. 12, 2015) [Docket 45-3], at 171:19–23). Plaintiff's counsel questioned Dr. Culligan as follows:

> Q: Okay. So what you're going to say about the MSDS is that had, before reading the plaintiffs' experts' opinions, you -- you didn't know what an MSDS sheet was and that you've never consulted one. Are those the only two real opinions you're going to give on the MSDS sheet?
>
> A: Sure. . . .
>
> Q: Okay. Yeah. I mean, if we can agree those are the only two things that you're going to say is that you've -- you didn't know what one was before this litigation and that you never consulted one, then I can move on. . . .
>
> A: I see.
>
> Q: But if we can agree to that, then we're good?
>
> A: Okay. We're good.

Q: So we can agree to that?

A: Yes, we can.

Q: Okay.

(*Id.* at 171:16–172:23). Thus, the plaintiff's challenge lacks merit, and her motion with respect to Dr. Culligan's MSDS opinions is **DENIED**.

6. Opinions on Patient Brochure

Although the plaintiff argues that Dr. Culligan's opinions on any patient brochures should be excluded, BSC concedes he will not offer such opinions at trial. (BSC's Resp. re: Culligan [Docket 67], at 4 n.12). Thus, the motion with respect to this matter is **GRANTED**.

7. Opinions on FDA

Although the plaintiff argues that Dr. Culligan's opinions concerning the FDA should be excluded, BSC concedes he will not offer such opinions at trial. (*Id.*). Thus, the motion with respect to these opinions is **GRANTED**.

For the above reasons, the plaintiff's Motion to Exclude Certain Opinions and Testimony of Dr. Patrick Culligan [Docket 45] is **GRANTED in part** and **DENIED in part**.

C. Roger Goldberg, M.D.

The plaintiff seeks to exclude the opinions and testimony of Roger Goldberg, M.D. Dr. Goldberg is the Director of the Division of Urogynecology at NorthShore University HealthSystem and an Associate Professor of Obstetrics and Gynecology at the University of Chicago Pritzker School of Medicine. (Ex. B, Goldberg Report [Docket 47-2], at 1). He is a member of the board of directors for AUGS and is the co-inventor of the Uphold. (*Id.*). The plaintiff argues that Dr. Goldberg's opinions should be excluded because "they violate the standards for independence of study or publication within his area of science" and because they

are "based purely on his personal experience." (Pl.'s Combined Mot. & Mem. of Law to Exclude the Ops. & Test. of Roger Goldberg, M.D. [Docket 47], at 3). The plaintiff also raises qualifications and reliability challenges to Dr. Goldberg's proffered testimony.

1. Conflict of Interest

First, the plaintiff argues that Dr. Goldberg is biased in favor of the Uphold because he invented it and because he testified that he has been paid approximately $1.4 million from BSC since 2005. (*See* Ex. C, Goldberg Dep. (Dec. 13, 2013) [Docket 47-3], at 304:13–21). She argues that Dr. Goldberg has recused himself from participating in Uphold studies to avoid any perceived bias and that, as a result, his interest in the Uphold should also exclude his testimony here. I find such an argument unavailing under *Daubert*. Bias and witness credibility are appropriate topics for cross-examination. The plaintiff's motion with respect to this matter is **DENIED**.

2. Personal Experience

Next, the plaintiff argues that Dr. Goldberg's opinions on the Uphold's safety should be excluded as unreliable because they are based solely on his personal experience. In particular, the plaintiff quotes ten of Dr. Goldberg's opinions. I disagree and decline to exclude *all* of Dr. Goldberg's safety opinions based on this argument. Dr. Goldberg's relied-upon list plainly reveals that he also considered scientific literature in forming his opinions. (*See* Ex. B, Goldberg Report [Docket 47-2], at Ex. B). Dr. Goldberg states this fact in his expert report. (*Id.* at 2 (stating that his opinions "are based on [his] education, training, clinical experience, *and* review of medical and scientific literature") (emphasis added)). Thus, even if Dr. Goldberg testified or wrote that he based an opinion on personal experience—for example, stating, "[b]ased on my 15-year experience using mesh for treatment of urinary incontinence, and more than 6 year

experience using Uphold mesh for treatment of pelvic prolapse, I agree that polypropylene mesh is a safe surgical implant and has been transformative in providing positive patient outcomes"—his attached relied-upon list cannot be ignored. (*Id.* at 20). Moreover, some of the same opinions quoted and challenged in this section of the plaintiff's brief are also challenged in a more specific manner later in their brief. I will address those challenges below. Otherwise, I decline to impose a blanket exclusion on all of Dr. Goldberg's safety opinions on the reasoning that they are based on his personal experience. The plaintiff's motion with respect to this matter is **DENIED**.

3. Opinions on Complication Rate

The plaintiff argues that Dr. Goldberg's opinion that the complication rate for the Uphold is less than 3% should be excluded because it is based on a calculation of cases at his medical center and is not supported by any scientific studies. However, BSC claims that "Dr. Goldberg's *data was published by a peer-reviewed journal*" and attaches the study in support. (BSC's Opp'n to Pl.'s Mot. to Strike and/or Exclude Dr. Roger Goldberg, M.D. [Docket 65], at 9 (emphasis in original); *see also* Ex. 3, Manhan K. Vu et al., *Minimal Mesh Repair for Apical and Anterior Prolapse: Initial Anatomical and Subjective Outcomes*, 23 Int. Urogynecol. J. 1753, 1753–61 (2012) [Docket 65-3]).

The plaintiff makes several arguments in her reply as to why this opinion is still unreliable. For example, she argues that "only a subset of the data was included" in the Vu study and that approximately 40% of all of the data from his center has not been published yet. (Pl.'s Reply to Def.'s Resp. to Pl.'s Combined Mot. & Mem. of Law to Exclude the Ops. & Test. of Roger Goldberg, M.D. [Docket 94], at 3–4). However, these arguments are without merit. Under *Daubert*, I need not decide whether a peer-reviewed article is accurate. Such questions are appropriately addressed on cross-examination. This aspect of the plaintiff's motion is **DENIED**.

4. Opinions on Physical Properties of Polypropylene

The plaintiff argues that Dr. Goldberg's opinions on the properties of the polypropylene mesh used in the Uphold—namely, that the mesh does not degrade, contract, or encapsulate—should be excluded. I agree and **EXCLUDE** his opinions as unreliable. Even if Dr. Goldberg considered the scientific literature and his clinical experience here, his expert report reveals flaws in his method. In his report, Dr. Goldberg writes that claims of mesh contraction, mesh degradation, and mesh infection "are wholly inconsistent with [his] clinical experience with not only the Uphold device but also a 15-year career performing thousands of mid-urethral slings utilizing the same type of mesh." (Ex. B, Goldberg Report [Docket 47-2], at 17). He "ha[s] not encountered either a single case of sling infection, or any case suggesting delayed contracture or delayed urinary retention." (*Id.*; *see also id.* at 19 (stating that he has never seen contraction in his practice and, thus, contraction "does not occur in any clinically relevant or detectable manner")). He states that "[m]y experience matches that of other experienced colleagues throughout the world," yet only references one article for his opinion that contraction does not occur and another article for his contention that polypropylene does not degrade. (*Id.* at 17–19).

Dr. Goldberg's lack of personal experience observing these alleged complications is not a scientific reason to reject contrary claims. While experience can be "the predominant, if not sole, basis for a great deal of reliable expert testimony," the court must ensure that the expert can "explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee notes. "The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" *Id.* (citation omitted). Dr. Goldberg has never even removed an Uphold product. (Ex. B, Goldberg Report [Docket 47-2], at 19). Although he views this as

"speak[ing] volumes to its tolerability, and to the very favorable healing response of the mesh implant material[,]" (*id.*), I instead view this as a lack of support for his opinions. His opinions concerning the properties of polypropylene are **EXCLUDED**. The plaintiff's motion with respect to this matter is **GRANTED**.[24]

5. Response to Plaintiff's Experts' Claims

Lastly, the plaintiff argues that all of Dr. Goldberg's opinions in response to the plaintiff's experts' claims should be excluded because he is not qualified and his method was unreliable. Specifically, the plaintiff objects to Dr. Goldberg's opinions on (1) vaginal mesh implantation, (2) the MSDS, and (3) the severity of complications in the DFU.

a. Vaginal Mesh Implantation

First, the plaintiff challenges Dr. Goldberg's opinion that the plaintiff's experts are wrong in concluding that "the 'non-sterile' nature of the vagina makes transvaginal mesh surgery inadvisable" due to the presence of bacteria leading to infection. (*Id.* at 23). I agree with the plaintiff that Dr. Goldberg's method in reaching this opinion was unreliable. In his report, Dr. Goldberg makes broad assertions that "the Plaintiffs' claims of polypropylene mesh becoming routinely infected bears absolutely no resemblance to my experience, or to conventional wisdom shared by specialists providing care in this specialty." (*Id.*). He states that he "ha[s] not encountered a single infection of the mesh implant." (*Id.*). However, he cites to zero studies in this section of his report as a basis for rejecting the plaintiff's experts' opinions. As I explain above, my "gatekeeping function requires more than simply 'taking [Dr. Goldberg's] word for it.'" *See* Fed. R. Evid. 702 advisory committee notes (citation omitted). Even if Dr. Goldberg did consider scientific literature, as evidenced by his relied-upon list, his broad assertions fail to

[24] Because I find these opinions unreliable, I do not consider Dr. Goldberg's qualifications in the area of the properties of polypropylene mesh. *See* Fed. R. Evid. 702 (requiring an expert witness to be "qualified as an expert" *and* to base his testimony on "reliable principles and methods").

provide a reliable scientific basis for discounting contrary findings on this matter. Thus, his opinions are **EXCLUDED**.

b. MSDS

The plaintiff argues that Dr. Goldberg is unqualified to opine as to the MSDS for polypropylene mesh. In his report, he states:

> I have never used an MSDS in making clinical decisions, or in counseling patients on the risks or benefits of any medical treatment. Nor have I ever heard of any other surgeon using an MSDS in this manner. I have also seen no evidence that the MSDS to which Plaintiffs' experts refer is based on any medical or scientific evidence that raises any valid safety concern about the mesh used in the Uphold, or any other Boston Scientific Product.

(Ex. B, Goldberg Report [Docket 47-2], at 23-24). These are not expert opinions. Thus, I need not address them under *Daubert*. The plaintiff's motion with respect to this matter is **DENIED**.

c. DFU

Dr. Goldberg opines that "[s]urgeons are well aware of the clinical implications of complications such as infection, pain, erosion, and dyspareunia, including the potential for the complications to be serious or permanent, and the DFU provided an appropriate level of detail and scope of information." (*Id.* at 24–25). However, no source is cited in this section of the report, and there is no implication that Dr. Goldberg relied on scientific studies in making this particular blanket statement. Thus, Dr. Goldberg's opinion is **EXCLUDED** as unreliable. *See Daubert*, 509 U.S. at 590 ("Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known.").

Accordingly, as set forth above, the plaintiff's Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [Docket 47] is **GRANTED in part** and **DENIED in part**.

D. Gary L. Winn, Ph.D.

Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety

Management program at West Virginia University. Dr. Winn offers expert "opinions with regard to the nature and purpose of Material Safety Data Sheets (MSDS) generally, and specifically as to the MSDS for the polypropylene used by [BSC] in the manufacture of its pelvic mesh products." (Ex. A, Winn Report [Docket 48-1], at 1). The plaintiff argues that Dr. Winn's opinions should be excluded entirely, consistent with this court's decisions in *Tyree v. Boston Scientific Corp.*, __ F. Supp. 3d __, *63 (S.D. W. Va. 2014), *available at* 2014 WL 5320566, and *Eghnayem v. Boston Scientific Corp.*, __ F. Supp. 3d __, *61 (S.D. W. Va. 2014), *available at* 2014 WL 5461991, because his expert report is identical to the reports filed and excluded in those two cases.[25] In response, BSC contends that it "should be allowed to offer Dr. Winn's testimony and opinions to rebut MSDS related evidence presented by the Plaintiffs at trial." (BSC's Mem. in Opp'n to Pl.'s Combined Mots. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. [Docket 68], at 17). Specifically, BSC points to the transcripts from *Tyree* and *Eghnayem* where the plaintiffs' experts testified about the MSDS. (*Id.* at 15–16).

BSC has not presented any new arguments to convince me that Dr. Winn is warranted as an independent expert. However, I acknowledge the potential need for rebuttal testimony based on what the plaintiff presents at trial. Accordingly, I **RESERVE** ruling on the admissibility of Dr. Winn's expert opinions for trial.

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[25] In *Tyree*, I ruled as follows:

> In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form. Accordingly, I **FIND** that Dr. Winn's opinions regarding MSDSs should be excluded in their entirety.

2014 WL 5320566, at *63; *see also Eghnayem*, 2014 WL 5461991, at *61 (quoting *Tyree*).

E. Stephen Spiegelberg, Ph.D.

Dr. Spiegelberg is the president and co-founder of Cambridge Polymer Group, Inc., where he directs a team of scientists who perform contract research, analytical testing, and device development for the biomedical and polymer communities. Broadly, Dr. Spiegelberg opines that BSC's pelvic mesh products "are appropriate for their intended use in design and manufacture." (Ex. B, Spiegelberg Report [Docket 55-2], at 4). The plaintiff objects to the following general causation opinions offered by Dr. Spiegelberg: (1) general causation opinions regarding the position statements of medical organizations; (2) any matters related to the FDA clearance process; (3) opinions regarding the presence of black specks in BSC's mesh; and (4) opinions based on Fourier Transform Infrared Spectroscopy ("FTIR") and Energy Dispersive Spectrometry ("EDS"). I address these objections in turn.

1. Position Statements

First, the plaintiff argues that Dr. Spiegelberg's opinions regarding position statements should be excluded because (1) they are not contained in his expert report; (2) he is not qualified to offer such opinions; and (3) he lacks any reliable methodology. In response, BSC states that Dr. Spiegelberg does not offer opinions regarding position statements in either his expert report or his most recent deposition. Upon review, I agree with BSC that Dr. Spiegelberg does not in fact offer the opinions the plaintiff seeks to exclude. Accordingly, the plaintiff's motion with regard to position statements is **DENIED as moot**.

2. FDA

Next, the plaintiff contends that Dr. Spiegelberg is unqualified to opine on the FDA 510(k) clearance process and that such opinions should be excluded as irrelevant. In response, BSC concedes that Dr. Spiegelberg will not offer opinions on the FDA 510(k) clearance process.

Accordingly, the plaintiff's motion with regard to the FDA is **GRANTED**. BSC limits its concession by arguing that Dr. Spiegelberg is qualified to opine on ISO standards based on his "extensive experience in the field of medical device analysis and design." (BSC's Resp. in Opp'n to Pl.'s Mot. to Exclude the Ops. & Test. of Dr. Stephen Spiegelberg, Ph.D. [Docket 79], at 6). I agree. Dr. Spiegelberg's current work revolves around medical device development and consultation. (*See* Ex. B, Spiegelberg Report [Docket 55-2], at 2). He is also the Task Force Chairman for ASTM standards involving the cleanliness of biomedical devices and characterization methods for polymers. (*Id.* at 3). Consulting on the development of new medical products requires familiarity with the applicable industry standards. Therefore, to the extent Dr. Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so. Accordingly, the plaintiff's motion with regard to Dr. Spiegelberg's qualifications is **DENIED**.

3. Black Specks/Spots

Next, the plaintiff argues that Dr. Spiegelberg's opinions regarding black specks in BSC's mesh are unfounded and unreliable. In his expert report, Dr. Spiegelberg states: "I have reviewed information suggesting 'black spots' may appear in the polypropylene. These 'black spots' are actually reflections of light on the curves of the mesh when pictures are taken, rather than inclusions or defects in the mesh." (Ex. B, Spiegelberg Report [Docket 55-2], at 12). Dr. Spiegelberg elaborated on this conclusion in his deposition:

Q: And if I remember – do you remember what your opinion was in regard to black specks?

A: I do.

Q: Can you tell me?

A: The black specks that I observed in the meshes were not black specks per

> se, as in terms of inclusions, rather were just reflections that are often inherent in circular surfaces.
>
> Q: And did you perform independent testing to verify that?
>
> A: Yes, I did.
>
> Q: And could you describe that to me?
>
> A: You take the mesh and place it in an optical microscope, and then rotate the mesh under the optical microscope and see if the black specks move or disappear, which they did.

(Ex. D, Spiegelberg Dep. [Docket 79-1], at 17:22–18:14). The plaintiff contends that Dr. Spiegelberg's findings are unreliable because he did not review the photographs supplied by the plaintiff's expert, Dr. Dunn, nor did he take his own photographs. However, in his deposition, Dr. Spiegelberg testified that he did review Dr. Dunn's photographs. (*Id.* at 19:15). And whether Dr. Spiegelberg took his own photographs does not sufficiently undermine the reliability of his analysis here. Challenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black spots are better suited for cross-examination. Accordingly, the plaintiff's motion with regard to black specks/spots is **DENIED**.

4. FTIR/EDS

Last, the plaintiff seeks to limit Dr. Spiegelberg's general causation opinions based on his FTIR and EDS testing. However, the plaintiff also states that Dr. Spiegelberg's "admissions regarding the limitations of these techniques may also be grounds for cross-examination," and seeks only "qualification or explanation of the limitations inherent to these techniques" in order to avoid misleading or confusing the jury. (Pl.'s Mot. & Mem. in Supp. of Mot. to Exclude the Test. & Ops. of Dr. Stephen Spiegelberg, Ph.D. [Docket 55], at 11). The plaintiff will have the opportunity to adequately highlight these limitations at trial upon cross-examination. Accordingly, the plaintiff's motion with regard to Dr. Spiegelberg's FTIR and EDS testing is

DENIED.

In sum, the plaintiff's Motion to Exclude the Testimony and Opinions of Dr. Stephen Spiegelberg, Ph.D. [Docket 55] is **GRANTED in part** and **DENIED in part**.

F. Stephen F. Badylak, D.V.M., Ph.D., M.D.

Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a full Professor with tenure with the Department of Surgery at the University of Pittsburgh. Broadly, Dr. Badylak opines that the polypropylene mesh used in BSC's pelvic mesh products is biocompatible and safe for use in the human body. The plaintiff asks the court to exclude Dr. Badylak's (1) opinions related to the risk/benefit analysis or the safety and efficacy of BSC devices; and (2) opinions related to oxidative degradation.

1. Risk/Benefit Analysis or Safety & Efficacy

First, the plaintiff contends that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. In support of their argument regarding scientific literature, the plaintiff cites to a portion of Dr. Badylak's deposition where he "admitted" that he has not performed a "comprehensive review" of the literature related to specific BSC devices. (Pl.'s Mot. & Mem. of Law in Supp. of Their Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 57], at 7). However, Dr. Badylak's expert report indicates that he reviewed more than 200 relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. (BSC's Opp'n to Pl.'s Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 66], at 8; *see also* Ex. 2, Additional Materials

Considered for Expert Report [Docket 57-2], at Ex. B). Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. (*See* Ex. 5, Badylak Dep. [Docket 57-5], at 98:22–25); *see also Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991) (explaining that "a lack of specialization does not affect the admissibility of the opinion, but only its weight"). This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.

Similarly, the plaintiff's arguments regarding Dr. Badylak's clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. (*See* Ex. 2, Badylak Report [Docket 57-2], at 1). The qualification requirement of Federal Rule of Evidence 702 does not necessarily require specific clinical experience implanting the device at issue. *See Thomas J. Kline, Inc. v. Lorillard*, Inc., 878 F.2d 791, 799 (4th Cir. 1989) ("One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion."); *see also Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *4–5 (S.D. W. Va. July 8, 2014) (finding expert qualified to offer general causation opinions despite his lack of specific experience with the product at issue). Accordingly, the plaintiff's motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

2. Degradation

Lastly, the plaintiff argues that Dr. Badylak's opinions with regard to oxidative degradation based on the scientific literature are unreliable because he contradicted himself

during his deposition by acknowledging the "phenomenon" of oxidative reactions. (*See* Ex. 5, Badylak Dep. [Docket 57-5], at 108:2–6 ("I'm aware of the literature and the discussion, I'm aware of phenomenon of oxidative changes and oxidative reactions in the body everywhere, including the surface of biomaterials such as polypropylene, so yes, I've considered that. . . . As a matter of fact, I'm on record as saying oxidative reactions occur everywhere, including the surface of biomaterials."). However, the plaintiff omits Dr. Badylak's subsequent testimony, where he states: "What I don't believe is that these oxidative reactions at the surface of polypropylene are resulting in the degradation that's causing further problems. There's no evidence to suggest that exists." (*Id.* at 108:11–109:15). Upon review of the deposition, I do not find Dr. Badylak's testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiff's motion with regard to degradation is **DENIED**.

The plaintiff's Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 57] is thus **DENIED**.

VI. Effect of Daubert Ruling

I emphasize that my rulings excluding expert opinions under Rule 702 and *Daubert* are dispositive of their potential admissibility in these cases, but my rulings not to exclude expert opinions are not dispositive of their admissibility at trial. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule.

VII. Conclusion

For the reasons discussed above, my rulings on BSC's motions are as follows:

Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D. [Docket 34] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and

Testimony of Niall Galloway, M.D. [Docket 38] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 39] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Ron Luke, J.D., Ph.D. [Docket 40] is **DENIED as moot**; Motion to Exclude the Opinions and Testimony of Bobby L. Shull, M.D. [Docket 42] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Jimmy W. Mays, Ph.D. [Docket 44] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Russell Dunn, Ph.D. [Docket 46] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Bruce Rosenzweig, M.D. [Docket 49] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Peggy Pence, Ph.D. [Docket 50] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Richard Trepeta, M.D. [Docket 51] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D. [Docket 52] is **GRANTED**; and Motion to Exclude the Opinions and Testimony of Vladimir Iakovlev, M.D. [Docket 56] is **GRANTED**.

My rulings on the plaintiff's motions are as follows:

Motion to Exclude the Opinions and Testimony of Christine Brauer, Ph.D. [Docket 44] is **GRANTED**; Motion to Exclude the Opinions and Testimony of Patrick Culligan, M.D. [Docket 45] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Roger Goldberg, M.D. [Docket 47] is **GRANTED in part** and **DENIED in part**; Motion to Exclude the Opinions and Testimony of Gary L. Winn, Ph.D. [Docket 48] is **RESERVED**; Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. [Docket 55] is **GRANTED in part** and **DENIED in part**; and Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [Docket 57] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: April 28, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE